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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

DAE

h ch (pm)

The Honourable Mr. Justice S.G.M. Grange	Commissioner
P.S.A. Lamek, Q.C.	Counsel
E.A. Cronk	Associate Counsel
Thomas Millar	Administrator

Transcript of evidence
for

January 23, 1984

VOLUME 90

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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN
AND RELATED MATTERS.

3

4

Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Monday, the 23rd
day of January, 1984.

6

7

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

10

11

APPEARANCES:

12

P.S.A. LAMEK, Q.C.) Commission Counsel
E. CRONK)

13

T.C. MARSHALL, Q.C.) Counsel for the Attorney
D. HUNT) General and Solicitor General
L. CECCHETTO) of Ontario (Crown Attorneys
and Coroner's Office)

15

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I.J. ROLAND) for Sick Children
M. THOMSON)
R. BATTY)

18

B. PERCIVAL, Q.C.) Counsel for The Metropolitan
D. YOUNG) Toronto Police

19

W.N. ORTVED) Counsel for numerous Doctors
at The Hospital for Sick
Children

21

B. SYMES) Counsel for the Registered
Nurses' Association of Ontario
and 35 Registered Nurses at
The Hospital for Sick Children

23

H. SOLOMON) Counsel for The Ontario
Registered Nursing Assistants

25

(Cont'd)



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TORONTO, ONTARIO

(b)

APPEARANCES (Cont'd):

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6	B. KNAZAN	Counsel for Mrs. M. Christie - R.N.A.
7		
8	F.J. SHANAHAN	Counsel for Mr. & Mrs. Dominic Lombardo (parents of deceased child Stephanie Lombardo); and Heather Dawson (mother of deceased child Amber Dawson)
9		
10	W.W. TOBIAS	Counsel for Mr. & Mrs. Hines (parents of deceased child Jordan Hines)
11		
12	J. SHINEHOFT	Counsel for Lorie Pacsai and Kevin Garnet (parents of deceased child Kevin Pacsai)
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EMT.jc

A .

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--- On commencing at 10:00 a.m.

3

THE COMMISSIONER: Yes, Mr. Lamek?

4

MR. LAMEK: Thank you, Mr. Commissioner.

5

6

7

8

9

10

11

We have today, sir, something of a departure in that we have four witnesses. We have got a four for one today, and they are Drs. Smith, Wallace and Buehler who are three of the four authors of the so-called Atlanta Report, and Mr. Robert Kusiak, who is with the Ontario Government and provided skills of a statistician to the authors of the report.

12

13

Before I go on with that evidence, sir, perhaps I can say a couple of things.

14

15

16

17

18

The fourth of the authors of the report, Dr. Clark Heath, is as I think you know not available this week. He will be here if he is needed the beginning of next week, and I propose, sir, to proceed with three authors of the report who are here as a panel.

19

20

21

22

23

24

25

One of them, that is to say Dr. Smith, will provide most of the information with respect to the background and the initial involvement of the Centers for Disease Control and the Ontario Ministry and the Federal Government in this study, and I suggest that thereafter I and any other counsel who



A.2

1

2 may subsequently cross-examine either address
3 questions to the panel as a whole, leaving it to the
4 panel members to decide who should give the initial
5 response to the question, or address a question to
6 a particular member of the panel, and if that member
7 thinks that the question could more easily or
8 properly be answered by another member, he will so
9 suggest. But in either case either in the case of
10 a question to the panel or to a particular member,
11 once the question has been initially answered if
12 any other member of the panel disagrees with the
13 answer or wishes to add to it or explain it or
14 amplify it in any way, then I have suggested that
15 he or she feel free to do so, and in that way I
16 hope it will not be necessary to ask specifically
17 each time whether the other authors of the report
18 agree with the particular thing that has been said.

19

20 I think we may take it that if
21 there is any disagreement or desire to add anything
22 that will be forthcoming from the members of this
23 panel.

24

25 For the comfort of the Court
26 Reporters, I have asked each member of the panel
27 who speaks each time he or she does so to give a
28 name.

29

30



A.3

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2 THE COMMISSIONER: Yes.

3

4 MR. LAMEK: And that is going to be
a difficult thing I know to follow every time and I
think we must be alert --

5

6 THE COMMISSIONER: As long as we do
it the first few times.

7

8 MR. LAMEK: Yes.

9

10 THE COMMISSIONER: I think the
Reporters are smarter than the rest of us and will
catch on to that.

11

12 MR. LAMEK: Yes.

13

14 Now as I say Mr. Robert Kusiak is
15 also available to answer questions. He was not one
16 of the authors of the report but is a statistician
17 with the Provincial Government and he was seconded
18 to this study and he worked with the study team
19 contributing his statistical skills.

20

21 A particular word if I may, sir,
22 about Dr. Buehler. Clearly we are very grateful
23 for his having come here. We are grateful to the
24 Centers for Disease Control and the U.S. Department
25 of Health and Human Services for permitting him to
do so.

26

27 However, I understand representatives
28 of the Centers for Disease Control when they give
29

30



A.4

1

2 evidence in proceedings that do not involve the
3 Government of the United States do so under certain
4 clearly stated strictures, and in particular
5 Dr. Buehler is here as a fact witness to give
6 evidence as to his involvement in the study, as to the
7 design and execution of the study, as to the
8 actual conduct of the study and as to the conclusions
reached.

9

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He is not permitted and I know you
would not want him in any event to do this, he is
not permitted to give evidence as an expert witness
on matters of which he has no personal knowledge,
and he is in general terms required by his employer
not to answer hypothetical questions.

Dr. Buehler is accompanied by counsel
for the CDC, sir, Miss Verla Neslund, and I am
happy to introduce her to you, Mr. Commissioner.

I have been so bold as to speak
for you, sir, and to tell Miss Neslund that if I
or any other counsel should ask a question which
Dr. Buehler is not permitted to answer under the
terms of his employment, that you will permit her
to make the appropriate objection rather than
requiring her to make any comment through me or
anyone else.



A.5

1

2 I don't know if the witnesses have
3 been sworn but perhaps we could do that if they have
4 not.

5 THE COMMISSIONER: I wonder if perhaps
6 before we do that, has anyone any comments or
7 suggestions on this procedure which is certainly
8 not traditional. I have been bullied into it by
9 Mr. Lamek. If it doesn't work, if it becomes a
10 circus we will just have to go back to more
11 traditional lines, but this would help if it works,
12 and Mr. Lamek gets full credit. If it doesn't, I
13 think we can appropriately blame him.

14 MR. LAMEK: I will have to resign!

15 MS. SYMES: Mr. Commissioner, I am
16 not sure how it is going to work, but I would like
17 to reserve the right to make submissions to you with
18 respect to the conduct of cross-examination after
19 we see the order in which the evidence comes in
20 from the panel of witnesses.

21 THE COMMISSIONER: Yes. Well, you
22 can always do that.

23 THE COMMISSIONER: Anything else?
24 Well, you have started off well,
25 Mr. Lamek.

26 MR. LAMEK: So far so good.

27

28

29



A.6

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DR. LESBIA F. SMITH, Sworn
DR. JAMES WALTER BUEHLER, Sworn
DR. EVELYN MacKENZIE WALLACE, Sworn
MR. ROBERT KUSIAK, Sworn

5

DIRECT EXAMINATION BY MR. LAMEK:

6

Q. Dr. Smith, perhaps I could start with you in terms of background qualifications and so on. I understand that you were born in Puerto Rico and were at elementary school there?

(ANSWERS BY DR. SMITH)

10

A. Yes.

11

Q. You went to the United States for high school and university education in New York, and were graduated from State University of New York at Buffalo, in the School of Medicine in 1968.

14

A. That is right.

15

Q. With the degree of Doctor of Medicine?

16

A. Yes.

17

Q. Subsequently, your post-graduate training and internship at the Deaconess Hospital in Buffalo, residency from 1969 to 1973 there, essentially - not entirely there - but in internal medicine.

21

A. That is correct, yes.

22

Q. 1970 to 1971 you spent at the Toronto General Hospital as a senior assistant

24

25



1 (ANSWERS BY DR. SMITH)

2 resident in internal medicine and you completed
3 your residency at other hospitals in Toronto?

4 A. That is correct.

5 (2) Q. You have taken a number of
6 graduate courses related to the work which you now
7 do, and since 1981 you have been a senior medical
8 consultant in environmental health with the Ontario
9 Ministry of Health and concerned particularly with
10 environmental epidemiology, investigations of out-
11 breaks and surveillance of potential situations I
12 take it?

13 A. That is correct.

14 Q. You have provided me with a copy
15 of a curriculum vitae from which I have obviously
16 been extracting information and would you so identify
17 it, please?

18 A. Yes.

19 MR. LAMEK: May that be the next
20 exhibit, sir?

21 THE REGISTRAR: Exhibit 319.

22 THE COMMISSIONER: Exhibit 319.

23 ---- EXHIBIT NO. 319: Curriculum Vitae of
24 Lesbia F. Smith.

25 MR. LAMEK: Q. Dr. Wallace, you were
born far away also in Edinburgh?

A. (Dr. Wallace): Yes.



A.8

1

2 (ANSWERS BY DR. WALLACE)

3

4 the University of Edinburgh and were graduated in
5 1967 with the degrees of Bachelor of Medicine and
6 Bachelor of Surgery?

7

A. Yes.

8

9 Q. You subsequently interned at
10 the Edinburgh City Hospital in internal medicine
11 and paediatrics and subsequently at the Queen
12 Elizabeth Hospital in Barbados in surgery and
13 gynecology?

14

A. That is true.

15

16 Q. At some point and I confess it
17 is not entirely clear from the curriculum vitae that
18 you provided to me, you came to Canada and you spent
19 the years from 1973 to 1980 in general practice in
20 Nova Scotia, and in 1980 moved to Toronto?

21

A. That is correct.

22

23 Q. In 1981 you became a field
epidemiologist with the Laboratory Centre for Disease
Control, Ministry of Health and Welfare of Canada,
and you were seconded to the Province of Ontario
working with the Disease Control and Epidemiology
Service of the Provincial Ministry of Health?

24

A. That is correct.

25



A.9

1

2 (ANSWERS BY DR. WALLACE)

3

you were in that capacity when you became involved
4 in the study with which we are concerned today?

5

A. Yes.

6

Q. That was a two-year appointment
7 with the federal Ministry, and upon its expiry in
8 1983 you became a consultant in the Division,
9 Department of Infectious Diseases of the Ontario
10 Ministry of Health?

11

A. Yes.

12

Q. And that is your present
position, is it not, Dr. Wallace?

13

A. Yes.

14

Q. And similarly could you identify
15 for me, please, a copy of the curriculum vitae that
16 you provided to me?

17

A. Yes.

18

THE COMMISSIONER: Okay. Thank you.

19

320.

20

--- EXHIBIT NO. 320: Curriculum Vitae of
Evelyn MacKenzie Wallace.

21

22

23

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B/DM/ko

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(ANSWERS BY DR. BUEHLER)

3

Q. Dr. Buehler, on days like
this you must wish you had stayed at home, you
were born in California I understand?

4

A. That is correct.

5

Q. And did your undergraduate
work in Biochemistry at the University of
California at Berkeley, and subsequently the
Medical School, the University of California,
San Francisco, and were graduated in 1977 with the
degree of Doctor in Medicine?

6

A. Yes.

7

Q. Subsequently you did an
internship in residency in Pediatrics in Phoenix;
and I can't refrain from mentioning this it sounds
intriguing, you spent a period of about eight
months, 1979 to 1980, as a General Medical Officer
at the Lyndon B. Johnson Tropical Medical Center,
Pago Pago, American Samoa. It sounds like a very
good way to take a break in a residency.

8

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You subsequently completed your
residency in Pediatrics at the University of
Oregon and hold the Diploma of the American Board
of Pediatrics as of February of last year.

Since 1981 you have been with the



B 2

1

2 (ANSWERS BY DR. BUEHLER)

3 Centers for Disease Control, initially as an
4 Epidemic Intelligence Service Officer in the
5 Field Services Division, and laterally, since July
6 of 1983, as a Medical Epidemiologist in the
7 Pregnancy Epidemiology Branch, Division of
8 Reproductive Health, in the Centers for Disease
Control?

9 A. Yes.

10 Q. You have listed publications
11 which I will not embarrass you by referring to, they
12 are included in your curriculum vitae. I ask you,
13 Dr. Buehler, could you identify that as a copy of
14 your curriculum vitae please?

15 A. Yes.

16 THE COMMISSIONER: Exhibit 321.

17 ---- EXHIBIT NO. 321: Curriculum Vitae of
18 Dr. James Walter Buehler.

19 MR. LAMEK: Q. And Mr. Kusiak,
20 you have the distinction I think of being the only
21 native born Canadian in the group.

22 (ANSWERS BY MR. KUSIAK)

23 A. Apparently.

24 Q. You I understand did your
25 undergraduate work at Queen's?



1

2 (ANSWERS BY MR. KUSIAK)

3

A. That's true.

4

Q. Where you did mathematics and
physics and graduated with first class honours in
the B.Sc. program in 1971?

5

A. That's true.

6

Q. And subsequently a Masters
in Mathematics at the University of British
Columbia?

7

A. That's true.

8

Q. And you are a member of the
Institute of Applied Mathematics and Statistics?

9

A. That is true.

10

Q. You are currently engaged in
a part time Masters Course in statistics at the
University of Toronto?

11

A. That is true.

12

Q. Since 1975 you have been with
the Provincial Government, as I understand it,
initially as a Statistician in the Chief Coroner's
Office; and subsequently with the Ministry of the
Attorney General and currently as I understand it
with the Ministry of Labour?

13

A. That is true.

14

Q. And you too have a list of

15

16



1

2 (ANSWERS BY MR. KUSIAK)

3 publications as set out on the curriculum vitae
4 which you provided, could you identify that for me
5 please?

6 A. Yes sir, that is it.

7 MR. LAMEK: Thank you.

8 THE COMMISSIONER: Exhibit 322.

9 ---- EXHIBIT NO. 322: Curriculum Vitae of
10 Robert Kusiak.

11 MR. LAMEK: Q. Now, as I said
12 earlier, I understand you, Dr. Smith, are going to
13 help primarily with the background and the investi-
14 gation that was carried on by the two Canadian
15 governments, the Ontario and the Federal government,
16 in the Centers for Disease Control.

17 Can you tell me please how did the
18 Ontario Ministry and to the best of your knowledge
19 the Centers for Disease Control become involved in
20 the matters which have exercised this Commission for
21 these many many months?

22 (ANSWERS BY DR. SMITH)

23 A. It is my understanding that
24 some time in late July Dr. Carver, on behalf of
25 the Hospital for Sick Children --

26 Q. I am sorry, that is what year?



1

2 (ANSWERS BY DR. SMITH)

3 A. That would be 1982.

4 Q. Yes.

5 A. -- on behalf of the Hospital for
6 Sick Children approached Dr. Conrad of the Centers
7 for Disease Control to ask him for advice and to send
8 a team perhaps to the Hospital to do an investigation
9 of the cardiac mortality which had occurred and which
10 had been under some scrutiny during the inquiry, the
Nelles inquiry.

11 Q. The preliminary inquiry?

12 A. The preliminary inquiry, yes.

13 Subsequent to that the Centers for Disease Control
14 advised I believe, I believe advised the Hospital
15 that they would have to be invited by the government
16 agency and both the Provincial and the Federal
17 government were approached to invite the Centers for
18 Disease Control officially to send a team here to
perform an investigation.

19 Q. And the investigation that
20 ensued, as I understand it, was a joint activity by
21 the Centers on your part on behalf of the Ministry of
22 Ontario, and Dr. Wallace who was seconded to the
23 Ontario Ministry but at that time an officer with
24 the Federal Government?

25



1

2 (ANSWERS BY DR. SMITH)

3 A. That is correct.

4 Q. Dr. Smith, I am showing to you
5 a copy of what appears to be a memorandum dated
6 September 3rd, 1982 from Dr. Conrad and Dr. Brachman,
7 a Director for the Centers for Disease Control, and
I notice a copy has been directed to you.

8 A. Yes.

9 Q. Did you receive a copy of that
10 memorandum at or about September 3, 1982?

11 A. Yes I did, I received a copy of
12 that on September 27th.

13 Q. And you have a copy before you
14 at the moment?

15 A. Yes, I do.

16 Q. And does that memorandum
17 accurately summarize, so far as you are aware, the
genesis of this investigation?

18 A. Yes sir.

19 Q. And the involvement of the levels
20 of government in Canada and the Centers for Disease
21 Control in Atlanta?

22 A. Yes.

23 MR. LAMEK: Mr. Commissioner, this
24 is a useful short summary and perhaps it might be

25



1

2 marked as the next exhibit please.

3 THE COMMISSIONER: Exhibit 323.

4 ---- EXHIBIT NO. 323: Memorandum from Office of
5 the Director of Field
6 Services Division,
7 Epidemiology Program Office
8 to Director, Centers for
9 Disease Control, September
10 3, 1982.

11 MR. LAMEK: Q. Dr. Smith, I have just
12 one question about it, about this memorandum, and it
13 is possible - and Dr. Buehler may be able to help,
14 in the first paragraph of the memorandum the writers'
15 record telephone, or discussion between Dr. Carver,
16 the Chief of Pediatrics, or the then Chief of
17 Pediatrics for the Hospital and Mr. Conrad, making the
18 request that you have described to us. The second
19 half of the first paragraph reads:

20 "From approximately March 1980 through
21 March 1981, 6 infants who had been
22 hospitalized for various cardiac
23 diseases died, and their deaths were
24 suspected to have been related to
25 excessive levels of digoxin."

I suppose I could have asked Dr. Carver
had I known about this at the time. Do you have any
information as to the infants to whom he referred in
referring to 6 infants who were suspected to have died

24
25



1

2 of digoxin - to have had excessive levels of digoxin?

3 (ANSWERS BY DR. SMITH)

4 A. At the time that I saw this
5 memorandum I had no idea what the numbers referred to.

6 Q. Dr. Buehler, is that something
7 you can help us with?

8 A. (Dr. Buehler): I can't help
9 you with that.

10 Q. You don't know?

11 A. (Dr. Buehler): No.

12 Q. Okay. That was the beginning
13 of the story and perhaps we can come back to fill in
14 the intervening bits, but let us move to the end of
15 it if we may.

16 The CDC through Drs. Buehler and Heath
17 and no doubt its support services and resources did
18 participate in the study, and the result was the
19 report which has become known as the "Atlanta Report".

20 I am showing to you, Dr. Smith, and
21 perhaps your colleagues would care to look at it too,
22 a binder which contains not merely the text of the
23 report with figures, appendices and so on, but also
24 bound with it from something called "Draft Terms of
25 Reference" dated August 9th, 1982, and then the keys
to the numerical codes which are used in the report



1

2 (ANSWERS BY DR. SMITH)

3 to identify patients and nurses.

4 Could you identify for me please, in
5 fact all the documents contained in that binder but
6 more particularly number 4, the report which you and
7 your colleagues produced?

8 A. This is the report.

9 Q. Yes, and there is a letter of
10 transmittal on the very front page?

11 A. That is correct. And these are
12 the draft Terms of Reference which were received I
13 believe on September 9th in my office.

14 Q. Yes?

15 A. From the Hospital for Sick
16 Children.

17 Q. And the keys to the codes which
18 are included and for which certain deletions have been
19 made so as to leave only the children in whom this
20 Commission is expressly interested?

21 A. These are the codes.

22 MR. LAMEK: Thank you. Could that
23 report be the next exhibit, please, and the other
24 reports bound with it?

25 THE COMMISSIONER: Exhibit 324.



Smith, Buehler,
Wallace, Kusiak,
dr.ex. (Lamek)

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--- EXHIBIT NO. 324:

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Draft Terms of Reference,
dated August 9th, 1982,
together with other reports
bound with it.



BmB.jc
C 1

2 (ANSWERS BY DR. SMITH)

3 Q Now, Dr. Smith, the transmittal
4 letter that is bound with the report is not dated.
5 Are you able to tell me please when was the report
6 delivered to the Ministry of Health?

7 A It was delivered on February
8 16th, 1982 at 2 p.m.

9 Q 1980 ... ?

10 A 1982.

11 Q 1983 I would think.

12 A 1983 at 2 p.m.

13 THE COMMISSIONER: I am sorry,
14 February 16th at ... ?

15 DR. SMITH: February 16th, 1983.

16 THE COMMISSIONER: This may be more
17 idle curiosity than anything else. Were you asked
18 not to date it or is it a custom? You certainly knew
19 the time and the date.

20 DR. SMITH: Yes. We were advised of
21 the time and date quite late on and we had every
22 intention of dating it that day and did not do so.
23 But that is the correct day, the letter had been
24 done the day before.

25 THE COMMISSIONER: But my question
26 was, were you asked not to date it?



C.2

1

2

3 DR. SMITH: No, we were not asked not
to date it.

4

THE COMMISSIONER: No.

5

6

DR. SMITH: That was an oversight on
my part.

7

8

9

10

MR. LAMEK: Q. The letter of trans-
mittal, Dr. Smith, is addressed to the Minister of
Health, the Honourable Larry Grossman, Q.C. Was the
report in fact delivered to the Minister?

11

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(ANSWERS BY DR. SMITH)

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C.3

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2 (ANSWERS BY DR. SMITH)

3 Q. A representative of the Attorney
4 General's Ministry and of the Coroner's Office?

5 A. Yes.

6 Q. Do you recall anyone else who
7 at that time received a copy of the report?

8 A. Yes, there were members of the
9 Police Department there as well.

10 Q. Now, could we look at the binder,
11 please. The first tab appears to be a memorandum
12 setting out draft terms of reference. It is dated
13 August 9th, 1982. You have told me I think that you
14 received this document at your office on August 9th,
15 1982?

16 A. No, we actually received it on
17 September 9th.

18 Q. September 9th, I'm sorry, my
19 mistake, you are right.

20 A. The first week of September,
21 not in August.

22 Q. Do you know whose draft this was?

23 A. At that time, and it is still
24 my understanding that this was put together by the
25 Hospital.

Q. Because it was merely a draft



C.4

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2 (ANSWERS BY DR. SMITH)

3 and the terms of reference as eventually stated
4 differed slightly. Could you turn with me please
5 to the preface to your report under Tab 4 in the
6 binder and there following the very first paragraph
7 are the terms of reference as stated by the authors
of the report?

8

A. That is correct, yes.

9

Q. And they speak for themselves.

10

I tell you, Dr. Snith, as I read them they are
11 substantially the matters that were referred to in
12 the draft terms of reference which you understand
13 to have been prepared by the Hospital as some
14 consolidation of items. Is there any particular
15 matter that you can now recall which was suggested
16 by the Hospital as a topic for investigation but
which your team decided not to investigate?

17

A. I believe that we addressed
18 all of their concerns but under No. 6 in the final
19 terms of reference this particular investigation
20 was submitted as a separate report, which was an
assessment of the Pathology Department.

21

Q. I see. Now, other than the
22 suggestion which came as you believe from the Hospital
23 for the terms of reference of the investigation, did

24

25



C.5

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2 (ANSWERS BY DR. SMITH)

3 anybody else contribute to the refinement or
4 eventual formulation of those terms of reference
5 other than the members of the investigative team?

6 A. I don't believe so.

7 Q. All right.

8 A. Only the team.

9 Q. Now, before going further into
10 the study and the contents of the report, Dr. Smith,
11 the initial request for the assistance of the Centers
12 for Disease Control appears to have come from the
13 Hospital and in particular from Dr. Carver. I under-
14 stand that Dr. Carver at one time had some association
15 with the Centers for Disease Control. Is that your
16 understanding as well? Perhaps Dr. Buehler can help
17 us with that?

18 A. (Dr. Buehler): Dr. Carver is a
19 former member of the Epidemic Intelligence Service.

20 Q. Which was the capacity which
21 you first occupied when you went to the Centers?

22 A. (Dr. Buehler): Yes, that is correct.

23 Q. Okay. Do you have any infor-
24 mation as to how long he was there and whether he was
25 operating as an epidemiologist at the time?

26 A. (Dr. Buehler): I cannot speak to
27 Dr. Carver's C.V.



C.6

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2 (ANSWERS BY DR. SMITH)

3 Q. Okay. Do you have any information as to that, Dr. Smith?

4 A. No, I do not.

5 Q. You told us that the CDC couldn't respond to the request that came from the Hospital unless the Canadian and Provincial Governments became involved and that happened. But the initial request came from the Hospital. Did the Hospital receive a copy of the report at or about the time that it was submitted to the Ministry of Health and received by the other people whom you have identified?

6 A. No, it did not.

7 Q. Was the Hospital or was anyone at the Hospital made aware by any member of the investigation team of the conclusions or the contents of the report?

8 A. Yes. As the investigations were taking place we kept Dr. Carver briefed on a regular basis, weekly or every two weeks. On the day that we presented the report to the Ministry Dr. Buehler and Dr. Heath met with Dr. Carver and it is my understanding and I believe Dr. Buehler can speak to the detail of that meeting.

9 Q. Well, perhaps Dr. Buehler can

10

11



C.7

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2 (ANSWERS BY DR. SMITH)

3 tell us about that, about that meeting?

4 A. Yes.

5 Q. Other than as you have told me
6 though in the regular briefings or communications
7 with Dr. Carver, were you yourself involved in any
8 subsequent discussion of the report with anyone at
the Hospital?

9 A. No.

10 Q. Dr. Buehler, I wonder if you
11 would be good enough to tell us what occurred on the
12 day of delivery of the report, your meeting with
13 Dr. Carver?

14 (ANSWERS BY DR. BUEHLER)

15 A. Well, we spoke briefly with
16 Dr. Carver that morning. Really, there was nothing
17 to tell Dr. Carver at the time that in substance he
18 wasn't familiar with before. We had never released
19 in detail to members of the Hospital the particulars
20 of the evaluation that was formed by Dr. Nadas or
21 Dr. Kauffman, and we did not release that information
22 at that time.

23 Q. All right.

24 A. I think it is important to keep
25 in mind the background under which the study was



C.8

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2 (ANSWERS BY DR. BUEHLER)

3 conducted and, that is, the study was conducted in
4 the sense of full co-operation and participation
5 with the Hospital and in a sense the Hospital to a
6 large extent was a co-participant in the study.

7

8 Q. And to the extent that Dr. Carver
9 may not thitherto have been aware of them, did you
10 on February 16th disclose to him the conclusions at
11 which you had arrived in your report?

12

13 A. Dr. Carver knew that we had
14 detected an increase in mortality rates at the
15 Hospital. He was earlier aware of the finding
16 concerning associations between members of the
17 Hospital staff and certain deaths. He was never
18 given the particular details of that, only in a
19 general sense.

20

21 Q. All right. Perhaps, Dr. Buehler,
22 you too could deal with this question. From
23 February '83 up until now has there been any
24 publication by the Centers for Disease Control of
25 the report or of any information about the study and
its conclusions?

26

27 A. There have been two brief
28 publications that deal with limited parts of the report.

29

30 Q. Yes.

31

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C.9

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2 (ANSWERS BY DR. BUEHLER)

3 A. The first was in April, 1983
4 at the Annual Epidemic Intelligence Service
5 Conference sponsored by the Centers for Disease
6 Control and at that time I presented a 10-minute talk
7 followed by a 10-minute question and answer session
8 which dealt with some of the general epidemiologic
9 findings.

10 In particular, we had been asked not
11 to discuss publicly any of the findings that dealt
12 with possible associations between Hospital personnel
13 and deaths and at that meeting and throughout that
14 part of the report.

15

Q. All right.

16

17 A. In November of the past year I
18 gave virtually the same talk at the Annual Meeting
19 of the American Public Health Association in Dallas,
20 Texas.

21

Q. And it is my understanding,
22 Dr. Buehler, that a paper describing the study and
23 some of its conclusions has been drafted for possible
24 publication. Is that so?

25

A. That is correct. We feel that
there are certain public health implications that



C.10

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2 (ANSWERS BY DR. BUEHLER)

3 deserve dissemination in the scientific form. We
4 have prepared a draft manuscript that is still at
5 the stage of a draft. In approximately June or July
6 of last summer we sent a copy of that draft to the
7 Hospital both as a matter of courtesy and to ask
8 whether or not they had any concerns about background
information concerning the Hospital.

(2)

9

10 Q. All right. I take it,
11 Dr. Buehler, that in neither of the talks which you
12 have given, nor in the draft paper for publication,
13 is there any reference to any association between
14 death and Hospital personnel?

15

16 A. We have been asked publicly did
17 we address that issue and we have said yes, we did
18 address that issue but we have avoided any discussion
19 of the results of that part of the investigation.

20

21 Q. Dr. Buehler, while I've got you
22 there answering questions, perhaps you could tell me
23 something perhaps I should have asked you when I was
24 talking about your C.V. with you. What is or what
25 are the Centers for Disease Control?



D/EMT/ko

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2 (ANSWERS BY DR. BUEHLER)

3 A. The Centers for Disease Control
4 is a federal agency of the United States Public Health
5 Service which is part of the Department of Health and
6 Human Services. The CDC is a federal agency which
7 is primarily responsible for preventing disease,
8 monitoring occurrence of disease and promoting health
in the United States.

9 In the United States health is a
10 responsibility of the individual states and the mission
11 of the CDC is to assist the states in promoting health
12 and preventing disease.

13 Q. While we are on definitions and
14 basic concepts like what is the CDC, help us all,
15 please, what is an epidemic?

16 A. I think in a general sense you
17 can say that an epidemic is an unusual increase in the
18 occurrence of a disease in a population.

19 Q. And I take it epidemiology is a
20 study of such situations and an attempt to discern
21 their causes when they occur?

22 A. That is correct. Epidemiology
23 is the study of the pattern in both health and disease
24 in populations. The purpose of that study is to
25 promote health and to prevent disease.



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D 2

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Q. Dr. Smith, to help me with those
basic concepts you earlier furnished to me a definition
of epidemic and a skeleton outline of the approach to
the investigation of a suspected epidemic together
with a copy of a textbook chapter entitled "The
Practice of Epidemiology".

7

8

9

10

I had asked you for some basic help and
you were good enough to provide it. Is that the
material you provided to me and it has been distributed
to all parties?

11

(ANSWERS BY DR. SMITH)

12

A. Yes.

13

14

15

Q. Are you satisfied that for a
neophyte like myself that is of some assistance in
understanding at least the starting point from which
we will take off today?

16

17

A. Yes, that was the purpose of
that.

18

MR. LAMEK: Thank you.

19

THE COMMISSIONER: 325.

20

--- EXHIBIT NO. 325: Pages 315-318 "The
Practice of Epidemiology"
and outline referred to.

21

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MR. LAMEK: Q. Now at this point
perhaps I could address questions to the three or four



D 3

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2 of you at large and you decide who should answer the
3 thing primarily on the understanding as we have said
4 earlier that if anyone has anything to add by way of
5 disagreement, amplification, explanation and so on,
6 I may expect to hear from you.

7 When did the investigative team, the
8 core of the investigative team, that is to say the
9 three of you and Dr. Heath, first get together?

10 (ANSWERS BY DR. SMITH)

11 A. Our first meeting was on
12 September 8th, 1982 at the Hospital for Sick Children
13 in the office of the Administrator, Mr. Stibbards.

14 Q. And how did you set about to get
15 a feel for the dimensions of the situation that you
16 were going to study?

17 A. We were first asked to meet with
18 various members of the staff of the hospital. We were
19 given a schedule for that day and for the following day
20 to meet with some half dozen individuals to learn about
21 the hospital, how it was run, the roles of each
22 department and so on.

23 Q. You say you were asked to do
24 that?

25 A. Yes.

Q. By whom?



D 4

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2 (ANSWERS BY DR. SMITH)

3 A. We were presented with that
4 schedule after our first meeting with the Administrator
5 so that we could become acquainted with the place.

6 Q. Now you refer I think to those
7 discussions on page number 5 in your report under the
8 heading "Interviews". You set out there that you met
9 with members of the hospital staff including
10 administration, pediatrics, cardiology, cardiac
11 surgery, pharmacology, laboratory, pharmacy, nursing
and housekeeping?

12 A. Yes.

13 Q. Now there is no reference to
14 pathology there but I understand you also had a
15 meeting with Dr. Phillips?

16 A. Yes, we did, and it is an over-
17 sight. It is acknowledged at the end.

18 Q. All right. I am sure he is not
hurt.

19 And you say:

20 "The purpose of these meetings was to
21 characterize the working environment
22 in various areas of the hospital, to
23 determine what information had already
24 been collected, and to identify
additional data sources."

25



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2 (ANSWERS BY DR. SMITH)

3 Now in the course of those meetings did
4 anybody express to you any views or state any theories
5 as to the probable or possible explanation for all or
6 any of the deaths that had occurred?

7 A. To my recollection in those
8 early interviews we did not discuss specific theories.

9 Q. All right.

10 A. Only description of events.

11 Q. All right.

12 A. As perceived by the people that
13 we interviewed.

14 Q. Fine.

15 DR. BUEHLER: May I add to that
16 answer?

17 Q. Yes, of course.

18 (ANSWERS BY DR. BUEHLER)

19 A. We subsequently met throughout
20 the periods that we were there on and off with other
21 members of the hospital staff, and as you might expect
22 we heard a number of different theories.

23 Q. Yes?

24 A. In addition one of our preliminary
25 meetings was with Mr. Tepperman from the Coroner's
Office. Mr. Tepperman did have some definite theories.



D 6

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2 (ANSWERS BY DR. BUEHLER)

3 Q. The theories were coming to
4 you from the beginning from I think it is Dr. Tepperman
5 at the Coroner's Office?

6 A. Excuse me, Dr. Tepperman.

7 Q. Your initial meetings at the
8 hospital were for the purpose and carried on in the
9 vein that is set out in the final paragraph - the
10 final sentence in the paragraph headed "Interviews"
11 on page 5. This was a fact finding mission about the
12 hospital, its structure, what is already known and what
other information might be available?

13 A. Yes.

14 Q. You refer in that paragraph
15 incidentally to meeting with the Coroner's Office -
16 Dr. Tepperman I take it - the Centre of Forensic
17 Sciences, the Toronto Metropolitan Police and the
Provincial Judicial Commission.

18 By that last reference do you refer to
19 the Dublin Committee which I think was then active?

20 (ANSWERS BY DR. SMITH)

21 A. Yes, that is correct. Justice
22 Dublin met with Dr. Heath only.

23 Q. I see.

24 A. Some time in this period.

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D 7

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Q. Can you tell me, please, what documentary material was furnished to you initially to help you with the study that you were embarking upon?

(ANSWERS BY DR. BUEHLER)

A. I think the first question we were interested in in attempting to answer was was there or was there not an increase in mortality rates on the cardiology service during this time.

Q. Yes.

A. The initial information that we requested was information on the number of deaths in the hospital, on the patient census in different areas of the hospital, and we initially requested charts of some of the patients in question so that we could look at them and begin to get a preliminary sense of what some of the issues were.

Q. I take it at a later stage you obtained or were given access to the medical charts of a large number of babies?

A. Yes.

Q. That is to say including those who had died in the period July 1980 to March 1981? Others from that period who didn't die?

A. (Dr. Smith): Yes.



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2 (ANSWERS BY DR. BUEHLER)

3 Q. Others from other periods who
4 did or did not die? I take it a large number of charts
5 were made available to you?

6 A. That is correct. We had
7 virtually unlimited access to medical records in the
8 hospital.

9 Q. Similarly I take it the hospital
10 made available to you where possible statistical infor-
11 mation and records that you required?

12 A. Yes.

13 Q. And I think you already said that
14 the co-operation you received from the hospital was
15 entirely satisfactory?

16 A. Yes.

17 Q. And I take it if you requested
18 material if it was available they supplied it to you?

19 A. Yes.

20 Q. You were provided too with work
21 space at the hospital as I understand it? Instead of
22 having three people saying yes I have had nobody saying
23 yes and a nod doesn't show up on the transcript.

24 (ANSWERS BY DR. SMITH)

25 A. Yes. We had initially
26 Mr. Gordon's office which was a very small office for



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2 (ANSWERS BY DR. SMITH)

3 one person but we all worked there for about two
4 weeks, and then we had a much larger office with every
5 facility.

6 Q. I wonder if Mr. Gordon knows
7 there are larger offices in the hospital!

8 By the time you were conducting your
9 study there was also an ongoing investigation by the
Metropolitan Toronto Police as we all know.

10 A. Yes.

11 Q. And I understand and I ask you
12 to confirm to me, please, that the Police also had
13 work space at the hospital at the time that you were
14 occupying your work space there?

15 A. That is right. They were just
down the hall.

16 Q. Can you tell me, please, what
17 contact if any there was between your group and the
18 police investigation team?

19 A. Well, we had a cordial relation-
20 ship. We had an initial meeting, just to meet them,
21 and we obtained from them records which they had in
22 their possession and that had been stamped - that had
23 been used in the preliminary inquiry, and they gave
us full access to the original records.

24

25



1 (ANSWERS BY DR. SMITH:)

2 had generated?

3 A. I do not recall requesting any
4 additional information from him, no.

5 Q. I take it that however Dr.
6 Kauffman as a consultant to the police clearly had
7 access to the complete file of toxicological informa-
tion about these children?

8 A. That is correct.

9 Q. In the work that he did for your
10 group was he permitted to disclose those data to you?

11 A. He was not and he did not.

12 Q. Was he permitted to use the
13 data in his work for you?

14 A. Yes, he was permitted to use
15 the data to formulate his overall conclusions.

16 Q. And therefore he might express
17 a conclusion on the basis of information of which you
18 were unaware?

19 A. That is correct.

20 Q. All right. But was it by
21 agreement with the police that he was permitted to make
22 use of the information although he was not permitted
23 to disclose the information to you?

24 A. That is correct.

25 Q. All right. Now, what did you ask



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2 perhaps Jim can elaborate on some of the meetings.

3 (ANSWERS BY DR. BUEHLER)

4 A. In our initial meeting with the
5 Police - to be precise I don't recall if it was our
6 initial meeting or a meeting shortly thereafter but
7 we were aware of their concerns about particular
nurses.

8 In addition, as you can imagine, many
9 of the particular records that we were reviewing were
10 records that they were reviewing, and so there was
11 often an interchange of documents.

12 Q. Yes?

13 A. We did as part of I would say
14 the cordial relationship we had with the Police, have
15 discussions with them, but in no way was the design of
16 our study or any decisions that we took in terms of
17 executing our study influenced by any discussion we
may have had with the Police.

18 Q. Perhaps we should go back to the
19 chronological sequence of this study then.

20 You have told me of the way in which you
21 set out to acquire information about the size and the
22 shape of the situation, and how you set about that
23 task. You have also said, Dr. Buehler, that the first
24 task was to establish whether indeed there had been an

25



12

1 (ANSWERS BY DR. BUEHLER)

2 epidemic of deaths I take it on the cardiology wards
3 in the period somewhere between the summer of 1980 and
4 the spring of 1981, and I take it the exact parameters
5 of the time period were not precisely defined at that
6 early stage, were they?

7 A. That is correct.

8 The first thing that we attempted to do
9 was to define a background rate of deaths on the
10 cardiology service beginning in January, 1976, through
11 to the summer of 1982.

12 Q. Yes?

13 A. And within several days of being
14 at the hospital using the hospital's monthly death
15 lists and the hospital monthly census information we
16 had generated a figure that resembled quite closely one
of the figures in the report.

17 Q. That is Figure 3?

18 A. That is correct, Figure 3.

19 The actual information in Figure 3 is
20 the result of a tremendous amount of effort to verify
21 those numbers, but we had a rough figure within just a
22 few days that was nearly identical in configuration
23 to Figure 3 as it appears in the text.

24 Q. We have seen here already several

25



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13 2 (ANSWERS BY DR. BUEHLER)

3 graphs plotting deaths, not only on the cardiology
4 ward but elsewhere.

5 To date we have seen graphs which plot
6 deaths in I call absolute numbers, raw numbers. This
7 graph as I understand it is expressed in mortality
8 rates.

9 Could you explain that concept for us,
10 please?

11 A. A rate by definition has a
12 numerator and a denominator in its calculation. In
13 this figure the rate is the number of deaths that
14 occurred during a given three month interval.

15 The denominator is the number of
16 patient days on the ward. A patient day could best be
17 defined by example if I were admitted to the hospital
18 and spent 10 days in the hospital I would contribute
19 10 patient days to the denominator.

20 Q. Yes?

21 A. Conversely if 10 people were
22 admitted and spent one day they would also contribute
23 10 patient days.

24 Q. In the aggregate they would
25 produce 10 patient days?

26 A. Yes.



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2 (ANSWERS BY DR. BUEHLER)

3 Q. And by expressing mortality as
4 a rate in that way I take it you can compare one
5 period with another without reference to the
6 particular population of the ward in numerical terms
7 at any given time?

8 A. We can compare one population -
9 we can compare the number of deaths at one time to the
10 deaths in another with respect to the number of patient
11 days.

12 Q. Yes?

13 A. The crude rate as these appear
14 do not offer any information as to the quality of those
15 patient days.

16 Q. Sorry; I don't understand that.

17

18

19

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21

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DM.jc

E

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2 (ANSWERS BY DR. BUEHLER)

3 Quality of the patient rates?

4 A. That is correct. For example,
5 if a population at one time were younger or more
6 severely ill --

7 Q. Yes.

8 A. -- that could affect the rates.

9 Q. Yes.

10 A. In addition to the number of
patients who are there at the time.11 Q. All right. In fact, as I under-
12 stand it then what you have done is merely put us
13 in a position where in terms of numbers one might
14 compare apples in Period A with apples in Period B
15 by expressing mortality as a number per 10,000
patient days, it is a rate?

16 A. Yes.

17 Q. You have not told us anything
18 in Figure 3, or indeed in this study, about the make-
19 up of the population of the ward at any particular
20 time, who was making up the 10,000 days and what
they have contributed to the mortality rate?21 A. We attempted to address that
22 issue.

23 Q. At a later stage though?

24

25



E.2

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2 (ANSWERS BY DR. BUEHLER)

3 A. Yes.

4 Q. But at this stage when you were
5 looking at mortality --

6 THE COMMISSIONER: I think you said
7 the report and I think you meant the figures, did you
not?

8 MR. LAMEK: I am sorry?

9 THE COMMISSIONER: You said you did
10 not in this report consider --

11 MR. LAMEK: I am sorry, in this study,
12 in this part of the report.

13 Q. In Figure 3 and the material on
14 page 5.

15 A. Yes.

16 Q. And your concern at the outset
17 was to establish simply in terms of mortality rates
18 whether there had been a real increase at any point
in the period at which you looked?

19 A. Yes, that is right, whether or
20 not there had been an increase.

21 Q. Looking at the raw numbers
there had apparently been an increase?

22 A. Yes.

23 Q. In the late summer/fall of 1980

24

25



E.3

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2 (ANSWERS BY DR. BUEHLER)

3 and the spring of 1981?

4 A. Yes.

5 Q. And by transferring that into
6 rates you were able to determine whether that apparent
7 increase was a real increase? Do I express that
correctly?

8 A. The word "real".

9 Q. Just so that I understand.

10 A. It is the word "real" that
bothers me.

11 Q. Okay.

12 A. It is not a word that is neatly
13 defined in an epidemiology investigation. The rate
14 is simply, it simply reflects the occurrence of
15 deaths with respect to the number of patient days at
16 risk or having the data, and our interpretation of
17 Figure 3 or a preliminary version which very much
18 resembled Figure 3 was that there had been an
19 apparent increase in the rate of deaths on the
cardiology wards.

20 Q. Well, I am puzzled by "apparent".
21 In terms of rate, the rate had increased had it not?

22 A. That is correct.

23 Q. Not just apparently increased,
24 it had increased?

25



E.4

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2 (ANSWERS BY DR. BUEHLER)

3 A. Yes.

4 Q. Okay. I will abandon "real" if
5 you will abandon "apparent", how is that?

6 A. Okay.

7 Q. At this time Mr. Kusiak, I think
8 we need to speak to you, because an increase I suppose
9 can be anything from one death per 10,000 to 50
10 deaths per 10,000. I take it what we are looking for
11 is something that is, I think the language is
12 statistically significant, is that right, Dr. Buehler?

13 A. Yes.

14 Q. Now what is statistical
15 significance, please?

16 (ANSWERS BY MR. KUSIAK)

17 A. Well statistical significance
18 is usually stated a little more in terms of
19 statistically significant as a certain probability
20 level.

21 Q. Okay.

22 A. And customarily that probability
23 level is chosen at 5 per cent. So the phrase usually
24 goes to this difference, or to this increase, whatever,
25 and is statistically significant at the 5 per cent
level. It is connected with the hypothetical



E.5

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2 (ANSWERS BY MR. KUSIAK)

3 situation. In this instance concerning the rates we
4 have the hypothesis that the rates in the epidemic
5 period, particularly during this nine-month period
6 were the same as the rates for some other period.

7 Q. Right.

8 A. So that all hypothesis is that
9 the rates are the same and the alternative to that
10 was that the rates were different. So the question
11 that was asked of me, what is the probability that
12 we would get such a high rate during this one-month
13 period, this one nine-month period given that there
14 is another rate during the preceding period, given
15 that difference, what is the probability that there
16 was no increase? Okay. And if this probability is
17 sufficiently small, in other words less than 5 per
18 cent, then one can conclude with a fair amount of
19 certainty that there was an increase therefore the
20 hypothesis that there was no increase was rejected,
21 is that clear?

22 Q. Reasonably I think. And perhaps
23 because I have heard it before. Was it your conclusion,
24 Mr. Kusiak, that there was indeed an increase in
25 the rate of mortality in the period which appears
to have begun in July of 1980, that was statistically
significant?



E. 6

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2 (ANSWERS BY MR. KUSIAK)

3 A. Yes.

4 Q. In that first paragraph under
5 the heading "Methods", it is set out that you
6 examined or calculated mortality rates not merely
7 for the cardiology wards, predecessor Ward 5A and
8 then Wards 4A and 4B, but for the Neonatal Intensive
9 Care Unit; and the Intensive Care Unit; the infant
10 medical wards in the Hospital at large. Can you
11 tell me please why mortality rates were calculated
12 for those locations?

13 (ANSWERS BY DR. WALLACE)

14 A. We wanted to ascertain exactly
15 where this epidemic was occurring, or this increase
16 in rates was occurring, was this general to the whole
17 Hospital, it wasn't specific to certain wards.

18 Q. And the results of those
19 inquiries are shown not only in Figure 3 at which
20 we have looked, but in Figure 4 and 5, those are
21 OR cardiac deaths; ICU deaths in Figure 6 for heart
22 patients? As a result of those inquiries and those
23 calculations, did you come to any conclusion as to
24 the place specific nature of the epidemic?

25 A. Yes, this epidemic was occurring
in Wards 4A and B.



E. 7

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2 (ANSWERS BY DR. BUEHLER)

3 Q. Did you at that stage draw any
4 distinction between Ward 4A and Ward 4B?

5 A. When we calculated rates
6 we combined Ward 4A and 4B.

7 Q. Yes.

8 A. The figure that you see, the
9 graph that you see in Figure 3 is the graph that
10 was obtained later, and it does show that there was
11 a greater increase in the mortality rate on Ward 4A.

12 Q. Was the increase in the
13 mortality rate that occurred on 4B statistically
14 significant, did you conclude there had been an
15 epidemic of some though perhaps smaller proportions
16 on 4B?

17 A. (Dr. Wallace): I think we found it
18 difficult to come to any definite conclusions.

19 Q. With respect to 4B?

20 A. May I add to that?

21 Q. Yes, of course.

22 A. I would like to direct your
23 attention to page 6.

24 Q. Yes

25 A. And what we have done here is
26 compare the rate of deaths on 4A/B together to the



E.8

1

2 (ANSWERS BY DR. BUEHLER)

3 corresponding nine-month period during the preceding
4 several years. We then compared the rate on 4A alone
5 to the rate during the preceding years and the rate
6 on 4B alone.

7

Q. That is the latter half of the
first paragraph on page 6?

8

A. That is correct. If you look
9 approximately three-quarters of the way down that
10 paragraph there is a sentence that reads:

11

12 "On Ward 4A during the epidemic
13 period, 8 deaths occurred per 4,401
14 patient days (18.2 deaths/10,000
15 patient-days) with one-five deaths
16 per quarter, and the relative risk
17 of death compared to the preceding
18 four years was 1.5 (95% confidence
19 limits - 0.7-3.2)."

20

21 What that means is that the rate of
22 deaths was one and a half times greater on Ward 4B
23 during that period when compared to the preceding
24 several years. The 95 per cent confidence limit in
25 a sense corresponds to what Mr. Kusiak described as
statistically significant. And if the 95 per cent
confidence limit excludes 1.0 we would say that that



E.9

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2 (ANSWERS BY DR. BUEHLER)

3 difference is significant. In this instance the
4 range of the 95 per cent confidence limit is 0.7-3.2.
5 So that on Ward 4B although there was a relative
6 increase of one and a half times that increase was
7 not statistically significant.

8

Q. Was the conclusion of that
9 that appeared to have been an epidemic specific to
Ward 4A?

10

A. Yes.

11

Q. And were you able by plotting
12 the rates, and perhaps you can refer again to Figure 3,
13 to define the period of that epidemic?

14

A. Yes.

15

Q. How was it defined?

16

A. We defined the epidemic period
as the interval between July 1980 through March 1981.

17

Q. Both inclusive?

18

A. Yes.

19

Q. In arriving at that conclusion
you made comparisons between different periods; and
indeed you have said you compared with the nine-month
21 period, July to March, corresponding periods from
other years. Why was it appropriate to use
23 corresponding July to March periods for comparison
purposes?

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E.10

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2 (ANSWERS BY DR. BUEHLER)

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A. We could have done that calculation either way, using the entire 4 to 5 year intervals preceding that, but we felt that because of the possibility of potential seasonal variations in deaths that we use the corresponding nine months. In this instance the conclusions would not have differed had we used the entire preceding 4 to 5 years.

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Q. Set out at the top of page 6 of the report under "Results" the mortality rates shown in Figure (3) for the period January 1976 to September 1982. In other words you went back a period of some four and a half years prior to the beginning of what eventually turned out to be the epidemic period and you went forward some one and a half years after the end of that epidemic period.

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Perhaps this is a naive question, does the imbalance of the lack of symmetry between the period examined prior to and that examined subsequent to the epidemic period cause any concern or cause any question to be raised by the validity of the conclusions?

A. (Dr. Smith): One really doesn't raise any concern, there might be the question of



E.11

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2 (ANSWERS BY DR. SMITH)

3 some interventions having taken place, but nonetheless
4 the comparisons can be made.

5 Q. I am sorry, what do you mean by
6 "interventions having taken place"?

7 A. There were some changes made on
8 the ward, so that as time goes by and certain changes
9 do take place, but it is still quite all right to
10 compare periods before an epidemic and after an
11 epidemic to the epidemic period, there is no specific
problem.

12 DR. BUEHLER: May I add to that?

13 MR. LAMEK: Yes.

14 (ANSWERS BY DR. BUEHLER)

15 A. It is very unusual in
16 investigating an epidemic to be in a situation of
17 beginning an investigation well over a year after the
18 event. In most epidemic investigations you are there
during or shortly after the peak.

19 Q. So you have no subsequent
20 experience, or very little subsequent experience to
21 look at in the normal case?

22 A. That is correct.

23 Q. This was rather more luxurious
24 than the normal situation?

25



E.12

1

2 (ANSWERS BY DR. BUEHLER)

3 A. It certainly was.

4 Q. Did you obtain, or did you
5 attempt to obtain information as to mortality rates
6 on cardiology wards, or perhaps other places in other
7 paediatric hospitals for purposes of comparison?

8 A. (Dr. Smith): We entertained that
9 as a possibility, but since there were not any
10 comparable hospitals in the province that we would
11 readily have access to we opted for comparing the
12 Hospital to itself for different periods and so on,
13 in the design of the studies that were subsequently
14 performed.

15 Q. Had information been available
16 from comparable paediatric hospitals that have
17 in any way strengthened the impressions you arrived
18 at, or would it have produced different impressions,
19 what would have been the significance of information
20 from other comparable hospitals?

21 A. If a comparable hospital had
22 experienced a similar peak of mortality one might be
23 able to conclude that something was happening in the
24 general population at large that would have affected
25 that peak, not just something in the Hospital. It
might have been a more general phenomena that would



E.13

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2 (ANSWERS BY DR. SMITH)

3 have affected more than one hospital.

4 Q. You were not able to get such
5 comparable information?

6 A. No, we were not.

7 DR. BUEHLER: May I answer that?

8 MR. LAMEK: Yes.

9 (ANSWERS BY DR. BUEHLER)

10 A. There really was no comparable
11 hospital in Toronto, this Hospital was a major
12 referral centre and as such there was no other major
13 cardiac centre in Toronto.

14 I think the other issue is we were,
15 by our preliminary findings and by the nature of the
16 problem in general, investigating the question of
17 what happened at this Hospital, we were not terribly
18 concerned with other --

19 THE COMMISSIONER: Excuse me, Doctor,
20 you said there was no other major cardiac, there are
21 of course, there is no other major paediatric
22 hospital in Toronto?

23 DR. BUEHLER: Yes.

24 THE COMMISSIONER: Would the assistance
25 of other cardiac hospitals be of any assistance to
you in this investigation?



E.14

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DR. BUEHLER: I think-in this
investigation I think not.

4

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MR. LAMEK: Q. Essentially what you
are saying, Doctor, as I understand it, you were
comparing the Hospital against itself, this period
as against other periods, this population as against
other populations in the Hospital itself?

8

A. (Dr. Buehler) That is correct.

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2 Q. Now, I am spending a long time
3 on this mortality rate study but as I understand it,
4 it was fundamental to the whole exercise in deciding
5 whether indeed there had been an epidemic. At the
6 bottom of page 6 you refer to the results of the
7 studies of mortality rates in the ICU. I notice
8 that that is for a different period of time. The
9 study there appears to have begun as of January, '78,
10 not January, '76 as with other areas of the hospital.
11 Is there a particular reason for that?

12

(ANSWER BY DR. WALLACE:)

13

A. Yes. The data source we used
14 there was supplied to us by Dr. Barker.

15

Q. Dr. Barker?

16

A. Yes.

17

A. (DR. SMITH) Yes, Dr. Barker.

18

(ANSWER BY DR. WALLACE:)

19

A. Who is in charge of the intensive
care unit.

20

Q. And was there no data prior
to January '78?

21

A. He didn't have this recorded.

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Q. Just going back for a moment to page 5. At the bottom of page 5 there is something that apparently you wanted to undertake but were unable to because the records were not available. You attempted to subdivide cardiac mortality rates by location into three separate categories: post-operative, post-catheterization and post-no procedure, but you couldn't do that because you couldn't get the patient-day denominator into those categories. Transfer information as to patients in the hospital I understand was just not available in the form that you required it.

A. (DR. SMITH) That is correct.

Q. Did the inability to undertake that portion of the study impair in any way the validity of the conclusion you reached as to there having occurred an epidemic.

(ANSWERS BY DR. BUEHLER:)

A. This is a very complicated issue. One of the initial things that we attempted to define when we arrived at the hospital was sources of information that would allow us to take into account possible differences in the patient population which may have explained any increase in mortality rates. If the patient population during that period were a



1 (ANSWERS BY DR. BUEHLER:)

2 younger population, if the patient population were
3 a more severely ill population or if there was a
4 change in relative percentage of patients who had
5 had surgery performed or catheterizations performed,
6 that might affect the mortality patterns.

7 We met exhaustively with members of
8 the cardiology data group, we met with the director
9 of medical records, with the director of the Admissions
10 Department, with the clinical computers department and
11 we explored a number of potential ways that we might
12 get that information. Unfortunately, the type of
13 information that we sought to subdivide our patient
14 day denominator was not available.

15 Q. Yes.

16 A. We engaged the cooperation of
17 the hospital's clinical computers department and
18 worked closely with one of their computer programmers
19 to try and determine whether or not the hospital had
20 computerized records which documented changes in the
21 patient's location or status during hospitalization.

22 To illustrate that, let me draw your
23 attention to figure 1. You can see from figure 1
24 that patients commonly moved from one location of the
25 hospital to another; for example, a patient may be
admitted to the cardiology ward, undergo an operation,



1 (ANSWERS BY DR. BUEHLER:)

2 return to the intensive care unit and then return
3 to the cardiology ward and that patient's clinical
4 status may be different before and after those events;
5 or a patient may start hospitalization in another
6 area, particularly the newborn intensive care unit,
7 undergo heart surgery and return to cardiology wards.
8 So that an individual patient may contribute different
types of patient days.

9 Q. Yes.

10 A. Pre-operative or post-operative.

11 Q. Yes.

12 A. We, as I mentioned, worked at
13 great length with the clinical computers department.
14 Eventually they produced a computer printout which
15 attempted to document those transfers in the patient
16 population. Unfortunately, when members of the team
17 attempted to verify that information we felt that it
was not sufficiently adequate to use.

18 Q. Okay. When you say adequate,
19 you mean it was not always accurate, it was not
reliable?

20 A. Yes. I will refer that to Dr.
21 Smith.

22 Q. Okay.

23

24

25



1 (ANSWERS BY DR. SMITH:)

2 A. Yes. The information was not
3 always accurate.

4 Q. Okay.

5 A. We picked some of the names that
6 were documented on this list and went back to the
7 original charts to check to see how many patient
8 days had been contributed to different locations.
9 There were enough differences in the printout that
10 led us to believe we could not use the totals produced.

11 Q. All right. So, despite your
12 best efforts and the hospital's best efforts, the
13 data was simply not available to do this study?

14 A. That is correct.

15 Q. Dr. Duehler, I think the question
16 I asked you was, was the ability to do this study some-
17 thing which impaired in any way the validity of your
18 conclusion. With so much effort having been expended
19 to try and get this study done, it sounds to me as
though it was something fairly important to you.

20 (ANSWERS BY DR. BUEHLER:)

21 A. It is an important issue.
22 However, other results of the study that we will get
23 into later in terms of our conclusions are less
24 important and indeed there are other findings that
25 could not be explained on the basis of a more ill,



1 (ANSWERS BY DR. BUEHLER:)

2 more younger patient population.

3 Q. Okay. I take it then, as you
4 have told me, the result of the mortality rate
5 study was that you concluded that you were indeed
6 dealing with an epidemic of deaths, that the epidemic
7 had been place specific to the cardiology ward and
8 in particular to Ward 4-A and it appeared to have
9 occurred between July, 1980 and March of 1981, as you
have told me.

10 A. Yes.

11 Q. And I take it the next test
12 therefore was to seek an explanation for that epidemic.

13 A. That is correct.

14 Q. And that is the balance of the
study, is it not, trying to find an explanation?

15 A. Yes.

16 Q. And as I read the report, to that
17 end you undertook a number of studies, you considered
18 a multitude of characteristics and variables. Do I
19 take it correctly that you were looking for something
20 that linked those who died or, putting it the other
21 way, distinguished them from those who didn't and
22 distinguished them from those who had died or survived
23 in other periods of time in the hope of finding a reason
for the epidemic. Is that essentially what you were

24

25



1 (ANSWERS BY DR. BUEHLER:)

2 about?

3 A. Yes.

4 Q. Okay. Now, we will refer to
5 some of those studies but let me first digress for
6 a moment and deal with your retainer of experts and
7 consultants.

8 At what point did the team decide that
9 it needed to retain consultants to assist it in this
10 investigation?

11 (ANSWERS BY MR. SMITH:)

12 A. Very early on in looking at
13 our terms of reference we realized that the study team
14 did not have the expertise to deal with some of the
15 questions, namely, some assessments of clinical status
16 for which we would need a clinical cardiologist of
17 some eminence, that we would need a pharmacologist and
18 a toxicologist. So, fairly early on we realized that
19 we would need other consultants.

20 Q. Okay.

21 A. Within the first week.

22 Q. Within the first week. All right.
Indeed, because one of the terms of reference included
a review of the pathology department you also needed a
pathology consultant, did you not?

23 A. Yes, that is correct.



1 (ANSWERS BY DR. SMITH:)

2 Q. Yes. How did you go about
3 selecting your consultants?

4 A. The hospital had made some
5 recommendations for consultants.

6 Q. Yes.

7 A. And in addition Dr. Heath, who
8 I believe will be able to address the question more
9 accurately since it was he who searched for other
consultants in the United States.

10 Q. Yes.

11 A. Also provided some names, a
12 roster of names. We spoke to these people, at least
13 Dr. Heath spoke to these individuals and finally came
14 up with the names that we used: Dr. Nadis, Dr.
Kauffman and Dr. deSa.

15 Q. Dr. deSa in the pathology area?

16 A. That is correct.

17 Q. Can we consider Dr. Kauffman for
18 a moment, please. When your team approached Dr.
19 Kauffman had he already at that stage been retained
as a consultant by the Toronto Police?

20 A. We were not aware at the time that
21 we spoke to him that he had just been retained
22 approximately a week before by the police; but yes,
23 he had been.

24

25



1 (ANSWERS BY DR. SMITH:)

2 Q. When you discovered that did it
3 cause you any concern that he was indeed acting as a
4 consultant to the police?

5 A. It caused us some concern. So,
6 we therefore consulted with the police and we consulted
7 with Dr. Kauffman to see if we could work out an
8 arrangement which would suit everyone whereby he would
9 provide the expertise to both the police team and to
us without any conflict of interest.

10 Q. Can you tell me please what
11 toxicological information was available to your group;
12 toxicological information about the babies who had
died in this epidemic period. What did you have?

13 A. We had all the information that
14 was on the charts and, in addition, we had all of the
15 information which had been presented at the preliminary
16 inquiry which was excerpted into a single volume.

17 Q. Did you have direct access to the
18 information and results generated by Mr. Cimbura at
the Center of Forensic Sciences?

19 A. Not unless that information had
20 been presented at the preliminary inquiry.

21 Q. All right. Did you request any
22 additional information as to digoxin concentrations
23 and other toxicological information that Mr. Cimbura

24
25



1 (ANSWERS BY DR. SMITH:)

2 had generated?

3 A. I do not recall requesting any
4 additional information from him, no.

5 Q. I take it that however Dr.
6 Kauffman as a consultant to the police clearly had
7 access to the complete file of toxicological informa-
tion about these children?

8 A. That is correct.

9 Q. In the work that he did for your
10 group was he permitted to disclose those data to you?

11 A. He was not and he did not.

12 Q. Was he permitted to use the
13 data in his work for you?

14 A. Yes, he was permitted to use
15 the data to formulate his overall conclusions.

16 Q. And therefore he might express
17 a conclusion on the basis of information of which you
18 were unaware?

19 A. That is correct.

20 Q. All right. But was it by
21 agreement with the police that he was permitted to make
22 use of the information although he was not permitted
23 to disclose the information to you?

24 A. That is correct.

25 Q. All right. Now, what did you ask



1

2 Dr. Kauffman to do?

3 (ANSWERS BY DR. BUEHLER:)

4 A. We asked Dr. Kauffman to review
5 the available digoxin information and to form several
6 assessments. Dr. Kauffman's review of information was
7 limited only to those children who died during the
8 epidemic period as well as to one death which occurred
9 one day prior to the defined start of the epidemic
period.

10 Precisely what we asked him to do is
11 identified on page 12. First, we asked him to
12 develop a rating scale to assess whether or not death
13 was the result of digoxin intoxication. He answered
14 this using a one to five scale with one representing
least probable and five representing most probable.

15 Q. Yes.

16 A. In addition, we asked him
17 to attempt to perform judgments or assessments on
18 whether or not if digoxin intoxication was suspected
19 whether or not it was the result of a single acute
20 dose or multiple overdoses and whether or not he
21 felt there was information to suggest that other
22 medications may have contributed or modified the
response to digoxin.

23 Q. At the top of page 13 you

24

25



1 (ANSWERS BY DR. BUEHLER:)

2 record that:

3 "....the consultant attempted to suggest
4 possible routes and times of administra-
5 tion of overdoses in the four cases
6 where sufficient digoxin data to
7 support such estimates were available."

8 Is that something that he undertook or you requested of
9 him?

10 A. We requested that from him.

11 Q. Was the scoring system, the one
12 to five and so on, used by Dr. Kauffman one of his
13 devising or your devising or what? Was it imposed
14 upon him, did he design it himself, what happened to
15 that?

16 A. As I recall, we asked him to
17 use a scoring system and in appendix 1 is a detailed
18 description of the scoring system that he used.
19 Appendix 1 is taken verbatim from the report that
20 he made to us.

21 Q. Yes. I think you know Dr.
22 Kauffman has already given evidence here and we have
23 marked as an exhibit a binder of his returns to your
24 group, if you will, on the children with whom we are
25 concerned and if at any stage we need to refer to those
26 they are available for you.



1 (ANSWERS BY DR. BUEHLER:)

2 Can we just speak briefly of Dr.

3 Nadas, please. What was he asked to do?

4

5 A. We invited Dr. Nadas to give
6 his impressions as a clinician. We wanted him to give
7 us an assessment of children who died during the
8 epidemic period as well as children who died at other
9 times. The purpose of this assessment as well as other
10 information that we collected was intended to answer
11 the question, how did the group of children who died
12 during this nine month period differ from children who
13 died at other times.

14

15 The issues that Dr. Nadas addressed
16 were (1) the severity of the child's illness at the
17 time of admission to the hospital; (2) the child's
18 prognosis; (3) the timing of the child's death in
19 respect to the child's clinical status; (4) the
20 clinical pattern of death and whether or not it
21 resembled digoxin toxicity; lastly, whether or not
22 Dr. Nadas felt that a higher level of care may have
23 been desirable.

24

25



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2 (ANSWERS BY DR. BUEHLER)

3 Q. And in order to enable him
4 to carry out that test what material was made
5 available to Dr. Nadas?

6 A. We sent some preliminary
7 material to Dr. Nadas to inform him of the situa-
8 tion. In making his assessments he used the
9 Hospital charts.

10 Q. In the case of each child
11 was the entire chart available to Dr. Nadas?

12 A. Yes. The original version
13 of each chart was available.

14 Q. Did he come to Toronto to
15 review the charts?

16 A. Yes, he did.

17 Q. And in due course you
18 received his reports on the children?

19 A. That is correct, yes.

20 Q. I am showing to you a binder
21 of his reports on those children with whom we are
22 particularly concerned, and found at the beginning
23 of it is a blank form for cardiac death review,
24 and then followed by computer forms in respect of
25 36 children under review here.

26 Do you recognize that as being what



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1
2 (ANSWERS BY DR. BUEHLER)

3 I have described it to be?

4 A. Yes.

5 THE COMMISSIONER: 326.

6 ---- EXHIBIT NO. 326: Binder containing reports
7 prepared by Dr. Nadas.

8 MR. LAMEK: Q. Just for a
9 moment, looking, Dr. Buehler, at the blank form if
10 you will, starting at the page numbered 1 of the
11 binder, can you tell me who devised the form and
12 the questions on this that Dr. Nadas was required
13 to complete?

14 A. We worked on this together.
15 I drafted the initial form and then at the time
16 Dr. Nadas arrived we worked with him in developing
17 the particular scores.

18 Q. Right.

19 A. As far as status was con-
cerned, Dr. Nadas felt that three scores would be
20 appropriate and that the terms he used were satis-
factory, intermediate and critical.

21 In terms of prognosis the three
22 terms he used were good, guarded and poor.

23 Q. Good, guarded and...?

24 A. Poor, yes.

25 In terms of the timing of the child's



Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

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G3

2 (ANSWERS BY DR. BUEHLER)

3

death, this dealt with whether or not when a child
4 died fit with the child's condition at the time of
5 death, and there are three categories. First,
6 expected and consistent with clinical status,
7 unexpected but consistent with clinical status,
8 and lastly, unexpected and inconsistent with clinical
status.

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In terms of the nature of the
terminal events we, when we drafted the form, had two
categories. Dr. Nadas felt that a third should be
added so that we had inconsistent with digoxin
intoxication, consistent with digoxin intoxication
and consistent with special concern, the latter
category being those deaths Dr. Nadas had special
concerns that death may have been due to digoxin
intoxication as judged by the clinical pattern of
death.

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Lastly we attempted to address the
issue of whether or not the child should have been
receiving a higher level of care, and in addressing
this issue Dr. Nadas cautioned that his assessments
were based on the standards at his hospital which
differed from the standards at The Hospital for
Sick Children in that the hospital where he was the



1
2 G4 (ANSWERS BY DR. BUEHLER)

3 former Chairman of Cardiology has a much larger
4 number of intensive care beds.

5 Q. In relation to the overall
6 size of the hospital?

7 A. That is correct.

8 Q. Yes.

9 A. So that this is a relative
10 score and he cautioned that it not be used as a
11 judgment on the level of care or that it not be
12 used, rather, as an assessment of the judgment of
the physicians at the Hospital.

13 Q. Do I understand, and I need
14 to be clear about this, that Dr. Nadas' completion
15 of these forms reflected his assessment of the
clinical picture of each child?

16 A. That is correct.

17 Q. And was Dr. Nadas furnished
18 with any toxicological information, post mortem
19 levels or anything of that sort of digoxin concentra-
20 tions?

21 A. In our initial letter to
22 Dr. Nadas I believe that we did send him some
23 information on post mortem digoxin that had been
24 presented at the preliminary hearing.

25



G5

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(ANSWERS BY DR. BUEHLER)

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Q. Yes.

4

A. But he did not use that information in forming his clinical assessments.

5

Q. All right. He focused on what was in the charts I take it?

6

A. That is correct.

7

Q. Now we do know, though, that in some of the charts there is information as to post mortem digoxin concentrations. I think, for example, of Cook where assays were done at the Hospital immediately following the child's death.

8

Where such information was contained in the chart do you know whether Dr. Nadas took it into account in preparing his report on a child?

9

A. I cannot tell you exactly what information Dr. Nadas looked at in each chart.

10

Q. Okay. And finally with respect to Dr. de Sa, can you tell me briefly what was he asked to do, and I may tell you that his report is already marked as an exhibit in these proceedings although Dr. de Sa has not given evidence here.

11

(ANSWERS BY DR. SMITH)

12

A. Yes. Dr. de Sa -- we were

13



1
2 G6 (ANSWERS BY DR. SMITH)

3 presented with preliminary terms of reference by
4 the Department of Pathology which we felt were
5 fairly reasonable. We handed them to Dr. de Sa
6 and Dr. de Sa felt that he was comfortable
7 addressing each of the issues and went on to do
8 so by reviewing the autopsy reports and slides of
9 those individuals during the epidemic period on
whom autopsies had been performed.

10 Q. Yes. As a matter of
11 curiosity can you tell me, please, why his report
12 was submitted separately?

13 A. As I remember his report
14 had no contentious issues in it and we felt that
15 it should not be held back anticipating that there
16 might be a problem with our report once it was
received.

17 Q. I see.

18 A. We felt that the Pathology
19 Department had been very eager to have an external
20 accessor and that part at least should not be held
back.

21 Q. All right. Did that report,
22 the de Sa report, go to the Hospital?

23 A. Yes, it did.

24

25



1
2 G7 (ANSWERS BY MR. SMITH)

3 MR. LAMEK: All right. I want
4 to come back to the particular reports of the
5 consultants later, but first I want to get back to
6 the sequence of your investigation.

7 Is this, Mr. Commissioner, an
8 appropriate time to take the morning recess?

9 THE COMMISSIONER: Yes. We will
10 take twenty minutes.

11 --- recess.

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H/DM/ko 2

--- Upon resuming

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THE COMMISSIONER: Yes Mr. Lamek?

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MR. LAMEK: Thank you, sir.

5

Q. Before we move on can we just go back to something you said immediately before the break Dr. Smith. That was - you told me that Dr. de Sa's report had been provided to the hospital. Can you tell me when and where that occurred?

9

(ANSWERS BY DR. SMITH)

10

A. Approximately a month or so after the main report was - well, both reports were given to the Ministry. There was a meeting between the Attorney General, his representative, the Deputy Minister and representatives of the hospital as to whether or not they should receive a full report. At that meeting specific mention was made of the Pathology Report, and as I remember the report was given to the hospital at that time.

18

Q. Was Dr. Phillips at the meeting?

19

A. He was not at that meeting, no.

20

Q. Now, coming back to the sequence of the investigation; from page 7 of the report and for a number of pages following that there is reference to a number of studies of different elements and aspects of the affair. I would take it that certain of

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25



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(ANSWERS BY DR. SMITH)

3 those studies were probably going on at the same time,
4 proceeding in parallel, but generally does the report
5 set out the studies that were conducted and the course
6 of your investigation in a more or less chronological
sequence?

(ANSWERS BY DR. BUEHLER)

14 A. After noting that there was an
15 increase in the mortality rate on Wards 4A and 4B we
16 attempted to look at a wide variety of different
17 aspects of patient care and patient population to
18 attempt to give us any clues or ideas that might
 explain why an increase in mortality had occurred.

19 Q. And what was the significance of
20 this particular enquiry: "ward conditions and features
of cardiac population"?



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2 (ANSWERS BY DR. BUEHLER)

3 to the number of procedures performed, geographic
4 referral patterns for surgical patients, but in
5 general we didn't come up with anything that stood out
6 as an important change except for one aspect and that
7 was occupancy rates in the intensive care units.

8 Q. Could we come to that in just a
9 moment Doctor?

10 A. Yes.

11 Q. Can you tell me first please,
12 forgive me, some of these questions are awfully simple
13 minded, why were you concerned to establish occupancy
14 rates either in the ward or anywhere else in the
15 hospital, what was the purpose in establishing
16 occupancy rates?

17 A. For example, if there was a
18 sharp increase in the occupancy rate on the cardiology
19 ward that may have placed some stress on the delivery
20 of services.

21 Q. Okay. I take it then it was for
22 that same reason you were interested in looking at
23 nurses' workloads, availability of nursing staff and
24 so on, to see whether for one reason or another the
25 care resource may perhaps have been stretched a bit
thin at particular times, and this may have had an



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2 (ANSWERS BY DR. BUEHLER)

3 effect on the quality of care that was able to be
4 provided?

5 A. That is correct.

6 Q. Now when you refer to the
7 nursing workload and the relative availability of
nursing staff, you report on page 7 that you used:

8 "... data from a scoring system
9 employed by the nursing administration
10 to plan both daily and long-term
nursing assignments."

11 Is that we have heard referred to as the NARvel
12 scoring system?

13 A. Yes, it is.

14 Q. Which is an assessment as I
15 understand it of the amount of care that will be
16 required by each patient on the ward and therefore
17 the total floor population?

18 A. That is correct.

19 Q. Now, the final sentence of that
20 second paragraph on page 7, says:

21 "These ratios ..."

22 That is to say the NARvel scores:

23 "... are computed only for nursing
24 person-hours available on the 0730-
1930 hours shift."



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H 5 2 (ANSWERS BY DR. BUEHLER)

3 Was NARvel scoring not done for the night shift at all
4 or were records just not available?

5 A. There is two parts to the NARvel
6 evaluation.

7 Q. Right.

8 A. One is the actual assessment of
9 time required for care of the child. The second is
10 the calculation of the ratio which is the ratio of
time required to nursing hours available.

11 Q. Right.

12 A. That ratio was calculated only
13 for nursing hours available on the daytime shift.

14 Q. Was the first assessment made
15 with respect to nighttime shift as well?

16 A. That assessment was made each
17 night in anticipation of nursing needs the following
day.

18 Q. Was it made during the day in
19 anticipation of nursing needs for the night?

20 A. No.

21 Q. Were there any data available to
22 you, any data of any kind available to you, any data of
23 any kind available to you upon which you could form a
judgment as to the sufficiency of nursing staff on the



1

2 (ANSWERS BY DR. BUEHLER)

3 cardiology wards on the night shift?

4 A. Not in terms of this ratio.

5 Q. Were there other kinds of
information that were available?

6 A. (Dr. Wallace): There is a
7 nursing assignment book and we did review this book
8 and we noticed that on several occasions nurses had
9 been sent from the cardiology wards to other wards in
10 the hospital leaving one to suspect that they had
11 adequate coverage.

12 Q. Was there anything else that
13 led you to form any judgment as to the adequacy of
14 the nursing resources that were on at night?

15 (ANSWERS BY DR. SMITH)

16 A. In reviewing the nursing
17 assignment books there were many instances as well,
18 not only when nurses were shifted out of the wards to
19 other more needy wards, but where nurses were
20 transferred in because the ward needed them. We did
21 not take account of these events but it was our over-
22 all impression that if nurses were needed they would
23 be transferred in.

24 Q. Tell me, do epidemiologists
25 concentrate solely upon objective data, or are you also



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2 (ANSWERS BY DR. SMITH)

3 interested in subjective impressions, subjective
4 impressions of other people as a source of infor-
5 mation?

6 A. Yes, we are interested in
7 subjective opinions as well as objective data,
8 primarily objective data. Sometimes objective data
9 are helpful in formulating questions.

10 Q. Did you make any enquiry to
11 ascertain if there was any perception of inadequate
12 nursing coverage on the wards at night?

13 (ANSWERS BY DR. WALLACE)

14 A. As far as we know there were
15 no complaints from the nursing staff themselves that
16 they were understaffed.

17 Q. At the time you were considering
18 these questions of the nursing workload and the
19 availability of nursing staff and so on, were you
20 aware at that time that in the epidemic period there
21 was apparently a clustering of deaths in the hours
22 between midnight and 6:00 a.m.?

23 (ANSWERS BY DR. BUEHLER)

24 A. I am sorry, could you state
25 your question again?

Q. Yes. At the time you were doing



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2 (ANSWERS BY DR. BUEHLER)

3 this part of your work, assessing the nursing workload,
4 relative availability of nursing staff, were you at
5 that time aware that in the epidemic period there
6 appeared to have been a clustering of deaths between
7 midnight and 6:00 a.m. on the cardiology wards?

8 A. Yes we were.

9 Q. We have heard here from Dr. Rowe
10 and others that the staff cardiologist at the hospital
11 had the impression that there was a shortage of nurses
12 on the cardiology wards at night. In the course of
13 your interviews with the hospital staff, for example,
14 that you have told me about, did you become aware of
15 that impression, was that ever conveyed to you?

16 A. During our preliminary meetings
17 with physicians at the hospital we were told that in
18 the latter part of 1980 the hospital had a sense of,
19 or an awareness that there was an increase in deaths
20 on the cardiology service, that they had met with the
21 physicians and with nursing administrators and there
22 were a number of concerns that arose at that time.
23 One of them was the adequacy of nursing coverage.
24 Another was the adequacy of physician coverage.
25 Another was the potential need for an intermediate
level intensive care facility on the 4A/4B unit.



1

2 (ANSWERS BY DR. BUEHLER)

3 Our understanding from that was that there was an
4 increase in the physician coverage; there was - plans
5 were made to establish an intermediate level care unit.
6 I am not clear as to what specific plans were made as
7 far as nursing staff coverage at that time.

8

9 Q. Now so far as the population
10 size on the cardiology wards was concerned, your
11 conclusion is set out I think in the final sentence
12 of the last full paragraph on page 7, is it not:

13

14 "And adjusted for number of beds the
15 mean monthly admission rates were the
16 same for the two wards and no relative
17 increase or decrease in admission was
18 associated with the epidemic period."

19

20 Is that the conclusion at which you
21 arrived after considering occupancy rates both in and
22 out of the epidemic period?

23

24 A. (Dr. Wallace): That is right.

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23jan84 2 (ANSWERS BY DR. BUEHLER)

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3 Q. And if therefore some
4 increased occupancy rate might have produced some
5 stretching of the available nursing or medical
6 resources, that does not appear to have been
7 existent here, there was no such increased
occupancy rate that you were able to discern?

8 A. From the data we have, yes.

9 Q. From the data you had?

10 A. Yes. May I just amplify that
11 slightly?

12 Q. Yes.

13 A. If you look at the second
sentence in that paragraph.

14 Q. Yes.

15 A. "During the epidemic period
16 (July 1980 through March 1981), the
17 mean monthly occupancy rate for
18 Ward 4A was 67.6%..."

19 I will exclude what is in the parentheses.

20 "...and for Ward 4B, 70.3%. For
the July-March period..."

21 Q. I'm sorry, where am I looking,
22 Doctor?

23 A. The second sentence of that

24
25



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12 2 (ANSWERS BY DR. BUEHLER)

3 bottom paragraph on page 7.

4 Q. I'm sorry, I had already
5 moved on to something else. Yes.

6 A. "...the mean monthly occupancy
7 rate for Ward 4A was 67.6% and for
8 Ward 4B, 70.3%."

9 And then we look at that same occupancy rate for
10 the July to March periods for the preceding years.
11 For 1976-77 and 1979-80 those rates were, through
12 1979-80, they were 76.3 per cent, 75.7 per cent,
13 55.8 per cent and 58.8.

14 So it is clear that there were
15 fluctuations in the occupancy rates.

16 Q. Yes.

17 A. Yet at a time when there
18 were similar occupancy rates we had not observed
19 a similar increase in mortality and that is the
20 basis for that conclusion.

21 Q. Fine, thank you. You already
22 explained to me I think the reason for considering
23 and comparing the same block of nine months, that is
24 to say, July to March in different years, to take
25 account of any possibility of seasonal influences
upon admissions and that sort of thing?



Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

13

1 (ANSWERS BY DR. BUEHLER)

2
3 A. That is correct.

4 Q. Yes. You did conclude however
5 that at the bottom of page 7 there was an increase
6 in occupancy rates or high occupancy rates in the
7 intensive care unit. You say:

8 "Occupancy rates in the ICU were
9 generally high and often exceeded
10 67% (the desired maximum occupancy
11 rate expressed in intra-hospital
12 memoranda)."

13 And that desired maximum rate
14 was exceeded for all nine months during the epidemic
15 period compared to approximately 80 per cent of the
16 preceding 52 months?

17 A. Yes.

18 Q. What is the possible
19 significance of that finding, where might that have
20 led?

21 (ANSWERS BY DR. SMITH)

22 A. The possible significance of
23 that is that because of the high occupancy rate in
24 the ICU patients may have been discharged too early
25 to wards.

26 Q. Yes.

27

28



Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

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I4 2 (ANSWERS BY DR. SMITH)

3 A. Or, on the other hand, they
4 may not have been accepted to the ICU when they
5 needed to be transferred.

6 Q. And that I take it could
7 give rise to the possibility that children who
8 really were sick enough to be in the ICU because of
pressure and space were in fact on the ward?

9 A. That is correct.

10 Q. And I take it at greater risk
11 of death because of their condition?

12 A. Correct.

13 (ANSWERS BY DR. BUEHLER)

14 A. I would hasten to add however
15 that for 42 of the preceding 52 months nearly four
16 out of five in that condition were also present.

17 Q. Yes. Indeed, high occupancy
18 rates in the ICU appears to be a fairly constant
19 fact of life at the Hospital in the period that you
examined?

20 A. It seemed to be a common
21 problem that was more common during that nine-month
22 period.

23 Q. Yes. But nevertheless, the
24 high occupancy rate in the ICU in this period could have

25



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2 I5 (ANSWERS BY DR. SMITH)

3 contributed in some way to the increased mortality
4 rate on the wards and that is I take it something
5 that you had to consider and to examine and decide
6 one way or another if you could?

7 A. That is correct.

8 Q. How did you determine if the
9 high occupancy rate in the ICU did indeed have any
effects on the ward mortality rate?

10 A. One of the assessments which
11 we asked Dr. Nadas to make, one of the clinical
12 assessments was to advise us on whether a particular
13 patient should have received a higher level of
14 care, should have been transferred to the ICU as we
15 put it in the questionnaire but his interpretation
of that was, should receive a higher level of care.

16 Q. All right. Now, I must tell
17 you that my review of the Nadas material as contained
18 in the binder that we have made an exhibit tells me
19 that it was his view that 12 of our 36 children
20 should have been in the ICU at, and I assume he
means immediately before the time they died. They
21 were Cook, Dawson, Estrella, Fasio, Floryn, Gage,
22 Gardner, Hines, Inwood, Miller, Thomas and Warner.

23 MR. STRATHY: Could we have that
24 once over slowly, please.



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MR. LAMEK: Yes, of course. I

assumed everybody had done the same analysis. Cook, Dawson, Estrella, Fasio, Floryn, Gage, Gardner, Hines, Inwood, Miller, Thomas and Warner. So it appears that we have Dr. Nadas saying of the 36 deaths with which we are concerned 12 of those children in his view should have been in the ICU. Now, there is only one child in our 36 who died in the ICU and that was Pacsai and Dr. Nadas did not say in his report that he thought -- he thought Pacsai should have gone there earlier. Fully a third of the group of 36, according to Nadas, should have been in the ICU at the time they died.

Q. Did you regard that opinion as an indicator that the busyness of the ICU in the epidemic period may indeed have contributed to the increased ward mortality rate?

(ANSWERS BY DR. BUEHLER)

A. To answer that, let me direct you to Table 7.

Q. Yes.

A. Because I think that it is very important to keep in mind that Dr. Nadas' assessments were performed to compare children who



Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

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(ANSWERS BY DR. BUEHLER)

3

died at one time to those children who died at
another.

5

Q. All right. Table 7 occupies
two pages I think.

6

A. Yes. We are looking at the
second page of Table 7, the last table on that page.

7

Q. That is Higher Level of Care
Desired?

10

A. That is correct.

11

Q. Yes.

12

A. And in addition I think it
is important to emphasize that Dr. Nadas' scores
are based on the standards at his hospital and
therefore shouldn't be directly applied to the
standards at this Hospital, at The Hospital for
Sick Children.

17

Q. Yes.

18

A. If you look at Table 7, and
I will direct you to the subtotal of pre-epidemic
and post-epidemic patients, six of 20 patients
who died before or after the epidemic period, in
other words, 30 per cent, had a similar score. So,
our interpretation of that is that in judging the
population of deaths, the population of deaths during

24

25



18

1 (ANSWERS BY DR. BUEHLER)

2 the epidemic period as a group did not differ in
3 that regard from the population of children who
4 died during the comparison times.

5 Q. Okay, you are saying that
6 on Dr. Nadas' review, whether he is looking at
7 children who died during or outside the epidemic
8 period, he says in 30 to 33 per cent of all cases
9 to have been of the view that the child should
10 have been in the ICU at the time he died?

11 A. Yes.

12 Q. Okay. And there is nothing
13 unusual in that respect in the epidemic period?

14 A. That is correct.

15 Q. Okay.

16 A. I would like to add to that
17 as long as we are on the issue of the ICU that if
18 admission to ICU or limitation of admission to ICU
19 contributed to the epidemic, there are certain
20 patterns that you might expect that differ from the
21 patterns we observed, and I think we will get to that
22 in later testimony.

23 Q. Well, if I don't you be sure
24 that you do, Doctor, thanks.

25 (ANSWERS BY DR. WALLACE)

A. Could I just add something?



1

I9 2 (ANSWERS BY DR. WALLACE)

3 Q. Yes.

4 A. A test of statistical
5 significance giving this P value of .97, that is
6 not significant.

7 MR. OLAH: I'm sorry, Mr. Lamek,
8 but when the last witness speaks it is very difficult
9 to hear her.

10 MR. LAMEK: I'm sorry, if you could
11 move the microphone a little.

12 DR. WALLACE: I'm sorry.

13 MR. LAMEK: I think that will be
14 of great help, Dr. Wallace.

15 Could you say again what you just
16 said, please.

17 A. If you do a test of statistical
18 significance on the data given in that table the
19 P value of .97 is not significant.

20 Q. All right. And that is a view
21 that a resident statistician would share, is it?

22 A. (Mr. Kusiak) That is true.

23 Q. Yes, all right.

24 THE COMMISSIONER: Could we have
25 some definition of all of these terms? I would
like to just have a glossary and I don't think there



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3 one. What does SD stand for?

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MR. KUSIAK: Standard Deviation.

5

THE COMMISSIONER: Standard devia-
6 tion. What does it mean?

7

MR. KUSIAK: It is an indication of
8 the variability in the data. Is that clear? It
9 somehow measures data or there are uncertainties or
10 variability in data and it somehow gives an idea
11 of how variable the data is. A larger standard
12 deviation indicates that there is a greater variance.

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THE COMMISSIONER: Can you just tell me where you get it, where you get the standard deviation?

MR. KUSIAK: Well, one can estimate it based on population - on observed data.

For instance, in this case we are looking at occupancy rates on a monthly rate on a ward.

THE COMMISSIONER: Yes.

MR. KUSIAK: One would have these figures for a number of months and one can use formulas to calculate a standard deviation if one makes the assumption that the occupancy rates follow a certain kind of statistical distribution.

THE COMMISSIONER: The problem I am having - let's look at page 7. The second line under "Results":

"During the epidemic period ... the mean monthly occupancy rate for Ward 4A was 67.6%".

The standard deviation was 7.7%.

Now what does that mean? Let us take August or September; it would what, go up or it would go down 7.7%?

MR. KUSIAK: What it means, the specific --



J.2

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2 THE COMMISSIONER: What is the standard?

3

4 MR. KUSIAK: What it means specifically
5 is that if I took twice, two times the standard
6 deviation, roughly two times --

7

8 THE COMMISSIONER: Yes.

9

10 MR. KUSIAK: In other words 15.4.

11

12 THE COMMISSIONER: 15.4.

13

14 MR. KUSIAK: Added that and subtracted
15 that to the 16.7 -- the 67.6 mean, then 95% of the
16 values that I used to calculate the standard deviation
17 would be within that range. Only 5% would be further
18 away. So you can see that the smaller, that is the
19 tighter the spread of the data, the more concentrated
20 the data is --

21

22 THE COMMISSIONER: 95% would be plus
23 or minus the mean; is that right? 95% would be plus
24 or minus the amount of double the standard deviation,
25 plus or minus the mean, over, above --

26

27 MR. KUSIAK: You would take the
28 standard deviation, double it.

29

30 THE COMMISSIONER: Double it.

31

32 MR. KUSIAK: And add it to the mean
33 and then subtract it from the mean and you would
34 get two numbers. You would get the mean plus two
35 standard deviations.

36

37



J.3

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2 THE COMMISSIONER: Yes.

3

4 MR. KUSIAK: And minus two standard
5 deviations and that would give you the range, the 95%
range.

5

6 THE COMMISSIONER: What is the value
7 of that to us?

7

8 MR. KUSIAK: Well, it would indicate
9 that sometimes the occupancy rate could be quite high.

9

10 THE COMMISSIONER: Yes.

10

11 MR. KUSIAK: Or it could be up to
12 67.7 plus 15.4%.

12

13 THE COMMISSIONER: Around 83 or some-
14 thing like that?

14

15 MR. KUSIAK: Yes. And other times
16 it could be - you know, infrequently it could be quite
17 low. But it gives an idea of how variable these
18 data are.

17

18 THE COMMISSIONER: Yes. Those are
19 calculated from the actual figures I take it. You
take the actual figures on the ward?

20

21 MR. KUSIAK: That is true.

21

22 THE COMMISSIONER: That would give us
23 the mean but you are also giving us this standard
24 deviation so we know just how much it does vary?

24

25 MR. KUSIAK: That is right.

25



J.4

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THE COMMISSIONER: Is that the idea?

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MR. KUSIAK: That is right.

4

5

THE COMMISSIONER: All right. That
is one of my problems. I will have others.

6

Rather than use the term "range" -
of course the range will obviously mean the
range from the bottom to the top I take it? - why do
you use "range" some times and "standard deviation"
other times?

10

11

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13

MR. KUSIAK: The standard deviation
is calculated on the assumption that the data follow
normal distribution, common distribution used in
statistics.

14

In some cases examining the data
would show that this is not the case, and in an
attempt to get an idea how variable the data are
one uses a range. This gives the complete
variability of the data.

18

19

THE COMMISSIONER: Yes. All right,
thank you.

20

MR. LAMEK: I rather hoped, Mr.
Commissioner, you were going to ask for an
explanation of the final paragraph before "B. Results"
on page 7 because I haven't dared. The one that
talks about chi-square test, frequency in a cell,

24

25



J.5

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2 Fisher exact test. I think I will leave that to a
3 braver soul than I.

4 MR. ORTVED: The Commissioner knows
5 all that.

6 MR. LAMEK: Probably, yes.

7 THE COMMISSIONER: You could send a
8 small stated case to the Divisional Court.

9 MR. LAMEK: Am I entitled to assume
10 that I know what this means?

11 Q. On page 8 of the report you
12 consider the question of procedures, surgical
13 procedures and referrals, surgical procedures
14 including cardiac catheterizations.

15 Can I look at the question of
16 referrals, please, and particularly referrals from
17 cardiologists in Manitoba.

18 Why were you concerned to examine
19 that situation?

20 (ANSWERS BY DR. WALLACE)

21 A. It had been suggested to us by
22 members of the Cardiology Department that you were
23 having more referrals at that time which were making
24 greater demands on the services of the cardiology
25 unit.

Q. In light of your conclusion



J.6

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2 (ANSWERS BY DR. WALLACE)

3

4 that the occupancy rate did not vary significantly
5 from prior periods did it matter where the patients
6 were coming from?

7

8 A. No, I don't think so. However, we did address the question because they had a strong
9 impression that this was affecting their service.

10

Q. And what did you conclude?

11

12 A. Well, as we have stated on the report a number of these referrals was relatively
13 constant throughout '81.

14

15 Q. And does not, therefore, appear to have been a contributing element to the increased
16 mortality rate?

17

A. That is right.

18

19 Q. And in studying surgical
20 procedures what was your purpose?

21

(ANSWERS BY DR. BUEHLER)

22

23 A. This issue, we were attempting in a rough way, and I am emphasizing "rough way" to
24 describe the complexity of heart surgeries that were
25 being performed.

26

27 In our interview with the Chairman
28 of the Hospital Surgery Department, Dr. Trusler, we
29 asked him if he thought using the duration of surgery

30

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J.7

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2 (ANSWERS BY DR. BUEHLER)

3 was acceptable as a crude index of the complexity
4 of the surgical procedures, and he agreed. Therefore
5 we looked at the per cent of surgical procedures
6 that lasted longer than four hours. But I think it
7 should be kept in mind that that is certainly a crude
8 index of the complexity of surgical procedures being
9 performed.

10 Q. Yes.

11 A. And again in examining that,
12 we didn't see a sharp increase in the per cent of
13 those procedures coincident with the academic period.

14 Similarly in reviewing the log books
15 of the Surgery Department we realized that a number
16 of surgical procedures are performed and that some
17 of those are relatively simple procedures that have
18 a lower risk, particularly pacemaker procedures and
19 ligation of patent ductus arteriosus.

20 Q. Yes.

21 A. So we examined whether or not
22 there was a relative increase or decrease in the
23 percentage of total procedures represented by those
24 two procedures which are relatively lower risk
25 procedures as judged by the cardiologists, and
similarly the finding there was that no, there wasn't



J.8

1

2 (ANSWERS BY DR. BUEHLER)

3 a sharp change of the per cent represented by those
4 procedures coincident with the epidemic period.

5 Q. And that therefore did not
6 appear to be a candidate for a contributing cause to
7 the mortality rate?

8 A. Yes.

9 Q. You also considered the incidence
10 of Code 25 calls. You looked at those on a quarterly
11 basis from January, 1979 to March, 1982.

12 Q. What information was available with
13 respect to Code 25 calls?

14 (ANSWERS BY DR. WALLACE)

15 A. The only information available
16 was a log kept by the telephone operator.

17 Q. Internal telephone operator of
18 the Hospital?

19 A. Yes. This was the source of
20 data that we worked from on this. •

21 Q. What information was contained
22 in the log?

23 A. It simply contained the date
24 and the time of the call and the ward to which it
25 had been directed.

Q. Not the patient?



J. 9

1

2 (ANSWERS BY DR. WALLACE)

3

A. No, there was no patient
identification.

5

Q. You record that in the nine-
month epidemic period there were some 27 Code 25
calls to the cardiology wards.

7

I understand you were working with
what, 35 or 36 deaths in the period?

9

(ANSWERS BY DR. SMITH)

10

A. 56 altogether ward associated
deaths. 36 in the epidemic period.

12

Q. 36? I tell you I am aware of
5 patients who died on the ward in the epidemic
period for whom there was a "do not resuscitate"
order in effect and I believe on page 15 of your
report you also say 5 of the 36 were classified as
"do not resuscitate" about a little over a third of
the way down the page, and those 5 as I recall it
were Floryn, Heyworth, Leith, Murphy and Perreault.

19

I can only give you my best
recollection, but my best recollection is there
were resuscitation efforts on all the other children.
I don't know whether you have similar recollection
from your review of anything you took from the charts,
but obviously the mathematics don't compute if I am
right?

25



J.10

1

2

(ANSWERS BY DR. SMITH)

3

A. There may have been a resuscitation effort for which there was no Code 25 call. If the physicians were already on the ward --

4

Q. Right.

5

A. -- there might not have been a call put through to the operator.

6

Q. Were you satisfied that the data you received from the operator's log was complete and accurate?

7

(ANSWERS BY DR. WALLACE)

8

A. We had no way of knowing. We have to accept this data.

9

We did discover some inaccuracies in that she had used a 24-hour clock and had forgotten to change the date sometimes but --

10

Q. An easy thing to do, yes.

11

A. Minor things like that.

12

Q. Were you aware of any successful resuscitation attempts on the cardiology wards in the nine-month period?

13

A. We were aware of only one successful attempt in a child who subsequently died four days later.

14

Q. And this was Estrella?

15

16



J.11

1

2 (ANSWERS BY DR. WALLACE)

3 A. Estrella I think.

4 DR. BUEHLER: May I amplify that answer?

5 MR. LAMEK: Q. Yes.

6 (ANSWERS BY DR. BUEHLER)

7 A. - Later in the report we mentioned
8 the Code 25 calls again and there were Code 25 calls
9 for whom we could not identify the patient for whom
the call was made.

10 Q. Yes.

11 A. Therefore there may have been
12 more successful resuscitations.

13 Q. Correct.

14 (ANSWERS BY MR. WALLACE)

15 A. I think because the timing of
16 the call did not roughly correspond with the timing
17 of the death we would have to assume that these were --

18 Q. That there were more than likely
19 some successful ones?

20 A. Some successful, yes.

21 Q. With respect to the item at
22 the foot of page 8, nursing care, the conclusion
23 insofar as you were able to express one seems to be
24 in the second and third last sentences of the
25 paragraph:



J.12

1

2 (ANSWERS BY DR. WALLACE)

3 "Within the epidemic period, deaths
4 did not tend to occur on days with
5 relative under- or over-staffing.

6 However, these data reflected staffing
7 for the day shift only."

8 I understand from that language that
9 it was your conclusion with respect to the day shifts
10 at least any apparent under- or over-staffing of
11 nurses did not appear to be a determinant of the
12 occurrence of death? Is that one way of putting it?

13 A. (Dr. Buehler): That is correct.

14 Q. But there was no information
15 upon which you could draw a similar or indeed a
16 different conclusion with respect to the night shift?

17 A. That is correct.

18 Q. You then went on, on page 9, to
19 consider how sick this ward population was. Having
20 determined that it was not unusual in terms of its
21 occupancy rate, you then went on to consider its
22 relative degree of sickness. That is compared, of
23 course, with non-epidemic period populations.

24 It was for this study, was it not,
25 that you enlisted the aid of Dr. Rowe?

A. (Dr. Buehler): That is correct.



J.13

1

2 Q. You furnished to him information
3 about a large number of patients and you asked him
4 to assess the severity of illness and the prognosis
5 for each of those children?

6

(ANSWERS BY DR. BUEHLER)

7

A. Yes.

8

Q. Now Dr. Rowe has told us in the
course of his evidence here, indeed he has shown us
and we have marked as an exhibit, the nature and the
extent of the information that was provided to him
about any individual patient.

9

A. Yes.

10

Q. I understand that Dr. Freedom
was also involved at one stage in this particular
exercise, was he not? Can you tell me something
about that, about Dr. Freedom's involvement, and
whether it continued?

11

(ANSWERS BY DR. SMITH)

12

13

14

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A. We initially engaged Dr. Freedom
and Dr. Rowe to assess a sample of patients with
standard categories that had been published in a
large article in the New England Journal of Medicine.
I believe in total there were 16 categories, an A,
B, C, D classification through 1 through 4, and on
a sample of patients they would give each patient an



J.14

1

2

(ANSWERS BY DR. SMITH)

3

A plus a number --

4

Q. A letter and a number?

5

A. A letter and a number. Their
results varied considerably.

6

Q. As between the children?

7

A. From each other, yes.

8

Q. Were they each doing the same
group of children?

9

A. The same group of children.

10

Q. And there was not a good
correlation between their two assessments?

11

A. No, there was not.

12

There as I remember Dr. Rowe's comments
were that there were - or rather our comments were
that there were quite a few categories and that it
might be perhaps better to collapse the categories
somewhat to give a general description of the
prognosis and clinical assessment of these children
because the categories were too diverse.

13

Q. And I guess with four letters
and four numbers you had what, sixteen --

14

A. Sixteen different possibilities
so they would have had to be collapsed to make some
general categories.

15

16



J.15

1

2 (ANSWERS BY DR. SMITH)

3 Q. So were the categories therefore
4 broadened in some way?

5 A. Dr. Rowe prepared a different
6 set of categories with criteria for each category,
7 and we proceeded to give him a sample of patients
8 that he would assess using the specific criteria
9 which were developed, and we at that point decided to
10 use only his assessment with a narrower range of
11 categories.

12

13

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Q. So after the categories were revised it was just Dr. Rowe who did the scoring?

(ANSWERS BY DR. SMITH:)

A. That is correct.

Q. Was it not desirable to have the scoring to continue to be done by two people for the sake of each checking out to see what kind of a correlation they would get?

A. Well, we felt Dr. Rowe as the Chairman of the Department would have -- would be the authoritative person to give us an opinion and with his having devised the criteria we felt that he could be relied upon to do this.

Q. Did you adopt any techniques to check on his own consistency with himself, or check on the validity of his rates?

A. No, we did not do any internal comparisons.

Q. Did Dr. Rowe ever complain to you that the information supplied to him for this purpose was insufficient to enable him to form a reasonable view of the child's severity of illness or prognosis?

A. He commented that in some instances it might not be sufficient and we did not use



1 (ANSWERS BY DR. SMITH:)

2 those cases where he could not make an assessment.

3 (ANSWERS BY DR. BUEHLER:)

4 A. In addition to that next to
5 some of the assessments he placed a question mark to
6 indicate that he was less certain. However, we in
7 comparing our results used the value that he gave,
8 for example, B would give a value of 2 or 3
9 and he put a figure 2 and a question mark. We would
use 2.

10 Q. But in some cases where
11 he felt unable to explain any, he couldn't give it
12 any score.

13 (ANSWERS BY DR. SMITH:)

14 A. That is right.

15 Q. There were some cases he felt
16 unable to explain or give it any score.

17 A. That is right.

18 Q. And those obviously you could
not use.

19 A. We did not use.

20 Q. Can you give me any idea of the
21 approximate number of those?

22 A. I think we counted up about
23 834 and there was some number between 830, between
24 that and 870, perhaps that 30, I don't remember

25



1

2 (ANSWERS BY DR. WALLACE:)

3 A. I think the number was about 27.

4 THE COMMISSIONER: 27 what though?

5 Q. 27 Dr. Rowe felt he could not
6 attribute a score on the information available.

7 (ANSWERS BY DR. BUEHLER:)

8 A. Before we deal with specific
9 numbers in this part of the study, I think some
10 problems in the analysis of this part of the study
11 have been identified and I would like to address them
12 at the appropriate time.

13 Q. Why don't we do it now, Doctor?

14 A. In doing this study our intent
15 was to select a sample of patients who were admitted
16 to the hospital before, during and after the epidemic
17 period. Ideally it would have been desirable to make
18 that selection based on the entire group of infants
19 who started the hospitalization or who ended up at
20 some time during their hospitalization on the cardiology
21 ward.

22 However, based on the type of
23 information that the hospital had we were only able
24 to use for the study children who started on the
25 cardiology, we were not able to include in our sample
children who started for example in the NICU.



1 (ANSWERS BY DR. WALLACE:)

2 We selected a group of patients for
3 this study. In addition, we intentionally tossed into
4 the study a number of patients who we were particularly
5 interested in, who could not be included in the analysis
6 of the samples. Those patients --

7 Q. I'm sorry, for what purpose were
8 they put in?

9 A. I am sorry. Those patients were
10 the children who died during the epidemic period and
11 their surviving roommates, which we thought at
12 some stage might be helpful for another part of
13 the investigation. During the summer we gave our
14 raw data on this part of the study to Dr. Brian
15 Haynes from McMaster University. He reviewed our
16 raw data and checked our calculations and observed
17 that we made a mistake in the tabulation in this part
18 of the study. His conclusion was that we included into
19 the sample patients not only the sample patients but
20 also the patients that we had hand picked.

21 Q. The seeded ones, as it were?

22 A. Yes. That information became
23 available to Dr. Smith and Dr. Wallace, I believe, on
24 Thursday or Friday, and to me on Friday night. We spent
25 some time Saturday reviewing our data and we believed
that Dr. Haynes judgment in that regard is correct.



1 (ANSWERS BY DR. WALLACE:)

2 That indeed there were patients included in that
3 analysis who should not have been included.

4 Dr. Haynes in his comment went
5 on to describe the mistake we made and it appears
6 that there was some misunderstanding on his part
7 as to exactly who these seeded patients were.

8 Our conclusion from this part of the
9 study was that the children who were admitted to the
10 cardiology ward during the epidemic period represented
11 a younger group of patients; they represented a
12 group of patients who were more severely ill; they
13 represented a group of patients who had less favourable
14 prognosis for surviving hospitalization. We have not
15 had an opportunity to in detail retabulate our
16 findings, although we have no reason -- well, we have
not had a chance to retabulate our findings in detail
ourselves.

17 Dr. Haynes' tabulation led to somewhat
18 different conclusions. Those conclusions were that;
19 number 1, the children who were admitted to the
20 hospital at this time were not younger, they were
21 a population that was slightly more severely ill but
22 not to the degree that we had observed, and not to a
23 degree that was statistically significant; and
24 they were not a population that was -- they were not

25



1 (ANSWERS BY DR. WALLACE:)

2 children who were more likely to have less favourable
3 prognosis. In any event, that finding in no way changes
4 the major conclusions of the report.

5 Q. Now, again to be sure I understand
6 you: it appears that cases which you -- and I used
7 the term "seeded" into this sample.

8 A. Yes.

9 Q. For a rather different purpose,
10 you wanted them scored but for use in a different
study.

11 A. That is correct.

12 Q. And which you intended to remove
13 before the analysis was made.

14 A. That is correct.

15 Q. Were inadvertently left in the
sample.

16 A. That is correct.

17 Q. Had the effect of making the
18 epidemic period admissions appear to be younger as
19 a group than in fact they were; sicker as a group
20 than they in fact were; and with poorer prognosis
than in fact they were, if Dr. Haynes be correct.

21 A. That is correct.

22 Q. And so the conclusions that are
23 stated on page 10 in the third paragraph on the page,



1 (ANSWERS BY DR. WALLACE:)

2 are those conclusions which are drawn from the sample
3 with the inadvertent addition of the seeded cases?

4 A. That is correct.

5 In addition, in the fourth paragraph,
6 the paragraph that begins:

7 "The comparison of age, severity,

8 and prognosis ratings for 4-A and 4-B..."

9 Apparently Dr. Haynes did not repeat that part of our
10 analysis, so we cannot comment on whether or not those
conclusions are correct or not.

11 Q. Now, had your conclusions as
12 stated in the second full paragraph on page 10 been
13 correct, then I take it you would have been led to
14 consider, as indeed you were, whether the younger,
15 sicker population in the epidemic period contributed
16 to the increased mortality rate?

17 A. That is correct.

18 Q. If Dr. Haynes be correct, your
19 conclusions as expressed there are not valid, then
20 does it follow from that that the sickness and
21 prognosis and age characteristics of the epidemic
22 population was not a contributing element in the increased
23 mortality rate because there was no discernible dif-
ference?

24 A. There was a very slight



1 (ANSWERS BY DR. WALLACE:)

2 difference in the percentage who were more severely
3 ill; but yes, in general you are correct.

4 Q. You were proceeding on the
5 basis of these conclusions and therefore had to
6 consider whether the age, severity and prognosis
7 characteristics of the epidemic population may have
8 contributed to the increased mortality rate.

9 A. That is correct.

10 Q. Just one question, please, before
11 we leave this study. Were you able to observe, or
12 did the two reports not lend themselves to a comparison?
13 were you able to observe any correlation between
14 Dr. Rowe's scoring and Dr. Nadas' assessment of the
15 patients?

16 A. I think it is important to
17 highlight the differences in what those scores were.
18 Dr. Nadas' assessment of severity was an assessment
19 of severity of illness at the time the child was
20 admitted to the hospital and it was based on a review
21 of the hospital chart, undoubtedly looking at the
22 child's condition when he or she arrived at the
23 hospital.

24 In contrast, Dr. Rowe's severity
25 assessments were based on the child's age and list of
diagnosis at discharge. Similarly, the prognosis



1 (ANSWERS BY DR. WALLACE:)

2 scores differed. Dr. Nadas' assessment of prognosis
3 was a more general statement of prognosis, again
4 based on a review of the patient's entire hospital
record.

5 Dr. Rowe's assessment of prognosis
6 differed in that it was again based only on informa-
7 tion that was available from the discharge summary,
8 which again was age, discharge diagnosis and pro-
9 cedures performed. His assessment was intended to
10 address the issue, what was the prognosis for surviv-
11 ing hospitalization. So to a certain extent, actually
12 to a very large extent they are very different types
of scores.

13 Q. And neither really serves to
14 enhance the confidence level that you feel in the
15 other?

16 A. I don't think we could make
17 specific comparisons.

18 Q. Just one other thing before
19 we leave the question of the error that you pointed
20 out and the consequences of the correction of the
21 error, should the assumption of Dr. Haynes be
22 correct. The cases that you seeded into the sample,
23 as you have told us, for scoring for a different
purpose were cases of children who had died during the



1 (ANSWERS BY DR. WALLACE:)

2 epidemic period.

3 A. That is correct, and they were
4 the children who died during the epidemic period and
5 for each child the other children who were in the same
6 room at the same time for those that we could
7 identify.

8 Q. And the inclusion of those
9 cases for the purposes of the analysis had the effect
10 of making the epidemic population look younger, more
severely ill and with poorer prognosis.

11 A. Yes.

12 Q. The removal of those cases, should
13 Dr. Haynes be correct, makes them look less younger,
14 less severely ill, with a less poorer prognosis.

15 A. That is correct.

16 Q. Does it follow from that that
17 the seeded cases, the children who died, were
18 generally younger, more severely ill and with a
19 poorer prognosis than the sample population in the
epidemic period that you selected for analysis?

20 A. Yes, that is true, the seeded
21 patients included the children who died and their
22 roommates.

23 Q. Yes.

24 25 (ANSWERS BY DR. SMITH:)



1 (ANSWERS BY DR. SMITH:)

2 A. Yes, I would like to emphasize
3 that some of that seeded group included more survivors
4 from the roommate group than it did actual patients
5 who died.

6 Q. I take it if a child died, let
7 us say, in 418, and four other children with him, you
8 would include all five, would you?

9 (ANSWER BY DR. BUEHLER:)

10 A. That is correct.

11 (ANSWERS BY DR. SMITH:)

12 A. That is correct. So the overall
13 inclusion of this group certainly changed the con-
14 clusion in that study. I don't think that we can
15 say --

16 Q. You can't attribute that just
17 to the condition of the children who died.

18 A. Exactly, because there was a
19 large contribution of those who in fact survived.

20

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Q. Survived, thank you. So, at this stage you have compared the ward populations in the epidemic and non-epidemic periods for severity, prognosis, age; age I take it being an important consideration in prognosis?

(ANSWERS BY DR. BUEHLER)

A. Yes.

Q. Because we have heard here that young patients with congenital heart defects, if they are at risk of death tend to die within the first year of life. You then went on to compare the deaths in the epidemic period with the deaths outside the epidemic period. Is there some distinguishing feature or common characteristic, either way you like, between the children who died in this period and those who died at other times? Is there something different about this group? Is that what we are really looking for?

A. That is correct.

Q. And this was a study, as I understand it, which required the help of your consultants, Dr. Nadas and Dr. Kauffman?

A. Yes. To be precise, however, Dr. Kauffman's assessments were only performed on the 36 who died during the epidemic periods.



L. 2

1

2 (ANSWERS BY DR. BUEHLER)

3

Q. Right.

4

A. So therefore Dr. Kauffman's assessments could not be used in comparing epidemic to non-epidemic deaths since he didn't in general look at non-epidemic deaths.

5

Q. Now, was the object of this exercise to determine if you could with the assistance of Dr. Nadas whether the children who died in the epidemic period were more severely sick than those who died outside the epidemic period?

6

A. Yes. One of the questions we asked Dr. Nadas to address was severity of illness at time of admission. So, we were able to ask the question: was this group of children more severely ill when they entered the Hospital compared to children who died at other times?

7

Q. Because at the time you were doing this study you believed on the basis of your earlier conclusion that the overall population in the epidemic period was more severely ill than children in other periods?

8

A. I don't recall precisely whether or not we had completed our analysis of the other study. The general question of severity was one we

9

10



L.3

1

2 (ANSWERS BY DR. BUEHLER)

3

would have asked regardless of that issue.

4

children who died in the epidemic period more severely ill than those who died at other times is an important question in your study, I take it?

5

A. Yes.

6

Q. All right. Can you help me with something if you would, please, at the bottom of page 10 under:

7

"IV. Comparison of Epidemic-Period

8

Deaths to Deaths in Other Periods.

9

"A. Methods.

10

"Although questions of digoxin intoxication and overdose were central, it was not possible to formulate a case definition based on digoxin levels for two reasons."

11

Can I pause there?

12

A. Yes.

13

Q. Could you define case definition, please, what does that mean?

14

A. In an epidemiologic study of this type it is often useful to define a case of illness. I think it would be easier to answer in terms of analogy.

15



L.5

1

2 (ANSWERS BY DR. BUEHLER)

3

Q. Fine.

4

A. Let's say we were investigating an outbreak of diarrhea we would need to define what is diarrhea or what is toxic shock syndrome, a patient who meets certain criteria. One of the studies that we contemplated may have been to ask how did children who had digoxin-related death compare to other children. But we were not able to precisely define that because the types of information available concerning digoxin varied so widely and for some children there was no particular post mortem digoxin information.

13

Q. Right.

14

A. Therefore, we were not able to define the cases for investigation using indicators of digoxin toxicity that were uniformly available.

17

Q. Okay. How then did you - what was your case definition for this study then?

19

A. Not being able to define digoxin intoxication precisely we decided to ask a different question. The question that we decided to ask was: is the population of children who died during this nine-month period, the population of deaths, all the deaths, are the characteristics of this group of

24

25



L. 6

1

2 (ANSWERS BY DR. BUEHLER)

3 children who died during these nine months different
4 from the characteristics of children who died at
5 other times. That is the question that we were
attempting to answer.

6 Q. All right.

7 THE COMMISSIONER: Would this be a
8 good time?

9 MR. LAMEK: Yes indeed, Mr. Commissioner.

10 THE COMMISSIONER: Until 2:30 then.

11 ---- Luncheon adjournment.

12

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A
/PS

1

2 ---Upon resuming.

3

THE COMMISSIONER: Yes, Mr. Lamek.

4

deal with the study which is covered from the bottom
5 of page 10 and following pages in your report.

6

"Comparison of epidemic-period deaths
7 to deaths in other periods."

8 On page 11 of the report there is the first reference
9 to a subdivision of the general category of cardiology
10 associated deaths and there are a number of different
11 headings. Can you help me please as to why you
12 thought it was appropriate or necessary to make those
13 subdivisions?

14 (ANSWERS BY DR. BUEHLER:)

15 A. We divided deaths into several
16 different categories. We were interested in distinguishing
17 between deaths that might be related to events on
18 the ward as opposed to deaths that might be related
19 to events in the operating room.

20 Q. Yes.

21 A. In the broadest sense the
22 cardiology associated deaths were all deaths during
23 this three year period in which the patients spent
24 part or all of their admission on the cardiology ward.
25 Those cardiology deaths were further subdivided into



1

2 (ANSWERS BY DR. BUEHLER:)

3 four categories which in turn were aggregated into
4 two categories. Those were ward deaths and post
5 ward ICU deaths; in other words, if a child died on
6 the ward or if a child deteriorated and subsequently
7 died in the ICU they belonged to this ward associated
category.

8 Similarly, if a child died in the
9 operating room, an OR death, or in the ICU, after
10 leaving the operating room, those categories were
11 designated as OR associated deaths.

12 Q. Was there some maximum time
13 interval between the transfer from ward to ICU that
14 would qualify a death for post ward ICU death?

15 A. No. In other words, the child
16 might deteriorate and be transferred to an ICU and die
17 shortly thereafter or several days later. That would
still qualify as a post-ward ICU death.

18 Q. Okay. And in that same paragraph
19 you refer to the reference time.

20 A. Yes.

21 Q. It is referred to in two
22 successive sentences. Halfway through the paragraph:
23 "For ward-associated deaths, exposure
24 to medications and contact with ward

25



1 (ANSWERS BY DR. BUEHLER:)

2 personnel were determined in relation
3 to the onset of terminal events. The
4 reference time was defined as the time
5 of call for resuscitation or emergency
6 attention preceding death (for ward
7 deaths) or preceding transfer from the
8 ward to the ICU (for post-ward ICU
deaths)."

9 I am not exactly clear from those two adjacent
10 sentences just what the reference time was. Was it
11 the onset of terminal events or was it the call for
12 resuscitation efforts or did you treat those two as
the same thing?

13 A. In effect, we treated them as
14 the same thing.

15 Q. Although they may not necessarily
16 be quite the same thing, may they?

17 A. Well, it was important to have
18 a time that we could identify with clarity.

19 Q. Yes.

20 A. And in general the time that
21 the nurse or other ward personnel issues a call for
22 help is usually very well documented in the hospital
23 chart, whereas a child's deterioration may not be as
easily definable in terms of exactly when that began.



Smith, Buehler,
Wallace, Kusiak
dr. ex. (Lamek)

1

2 (ANSWERS BY DR. BUEHLER:)

3 So, for our purposes we felt it was important to have
4 a time that we could determine relatively precisely.

5 THE COMMISSIONER: In some cases, Doctor
6 there was a code 23 as well as a code 25. I know code
7 23 is just for the doctors.

8 DR. BUEHLER: Right.

9 THE COMMISSIONER: Did you count that
as the call for help or the code 25?

10 DR. BUEHLER: In general, we counted --
11 if there was a code 23 that preceded the code 25 we
12 counted the code 23 as the time. Quite often the
13 code 23 and code 25 were separated by a very brief
14 interval.

15 THE COMMISSIONER: Yes, all right.

16 MR. LAMEK: Q. And indeed, as you
17 pointed out this morning, there may not have been a
18 code 25 as such called; if code 23 were called and the
19 doctor were there and the child deteriorated further,
20 there may or may not have been a code 25 called but
21 resuscitation efforts started.

22 (ANSWERS BY DR. BUEHLER:)

23 A. That's right, that is correct.
That's why we worded that as time of call for emergency
attention which could have been a 23 or a 25.

24

25



1.

2 (ANSWERS BY DR. BUEHLER:)

3 Q. Right. Now, in the next
4 paragraph, at the beginning of the paragraph you refer
5 to the abstraction of information from hospital charts
6 in a format suitable for computer analysis. We have
7 bound and distributed two forms of documents. We have
8 numbered 1, although I understand at the point of time
9 it was prepared later, a form for the case control
10 study and as number 2 in the binder, although I under-
11 stand this was the original preparation, a form headed
12 Cardiac Death Investigation.

13 Could you first identify those two
14 documents and we will mark them.

15 A. Yes.

16 THE COMMISSIONER: Which is going in
17 first?

18 THE COMMISSIONER: Oh, they are bound
19 together all right.

20 MR. LAMEK: "Data Sheets used in the
21 preparation of the 'Atlanta Report'."

22 THE COMMISSIONER: That is 327?

23 MR. LAMEK: Yes.

24 ----EXHIBIT NO. 327: Brief entitled "Data Sheets used
25 in the preparation of the 'Atlanta Report'."

26 MR. LAMEK: Q. Can we turn to the second

27



1

2 (ANSWERS BY DR. BUEHLER:)

3 tab first, "Cardiac Death investigation". Can you
4 tell me for what purpose this form was devised?

5 A. This form was devised so that
6 we could have a uniform way of recording information
7 about deaths during the time period we were interested
8 in studying. It was for the purpose of abstracting
hospital charts.

9 Q. And calls for the supplying of
10 a wide variety of information: racial background
11 of the patient, how the child arrived at the hospital,
12 by ambulance, helicopter and so on, under the tunnel
13 from the Toronto General, non-cardiac anomalies that
14 were present, a host of questions about the clinical
15 condition and diagnoses, birth information in item
16 3 on page 5 of the report and information as to the
17 mother, information as to the hospital course and
18 diagnostic studies performed, information as to
surgery, type of death and so on, medication, route
of administration, time of administration.

19 Was it the intention in preparing this
20 form or questionnaire to obtain wherever possible any
21 and all information which had occurred to you might
22 possibly form any kind of a link or connection or
23 common feature between the children who had died in

24

25



Smith, Buehler,
Wallace, Kusiak
dr. ex. (Lamek)

1

2 (ANSWERS BY DR. BUEHLER:)

3 the period?

4 A. Yes.

5 Q. You tried to cover the waterfront
with all possible variations and elements and factors.

6 A. Yes, that is correct.

7 Q. Now, who actually did the abstract-
8 ing of the information from the charts and completed
9 the forms?

10 A. The three of us plus Dr. Madeline
11 Harris.

12 Q. And how many charts were so
13 abstracted?

14 A. (DR. SMITH) 134 for the
death/death comparisons.

15 (ANSWER BY DR. BUEHLER:)

16 A. 142.

17 A. (DR. SMITH) I'm sorry, 42.

18 Q. That was quite a task. And what
19 was the purpose, please, for the other form, the case
control study form?

20 (ANSWERS BY DR. BUEHLER:)

21 A. That form was from a subsequent
22 study we did where we looked at children who died and
23 compared them to other children who were in the same room

24

25



Smith, Buehler,
Wallace, Kusiak
dr. ex. (Lamek)

1

2 (ANSWERS BY DR. BUEHLER:)

3 at the time that they deteriorated.

4 Q. That was the roommate study?

5 A. The roommate study, correct.

6 Q. Why are there two different
forms and why are they different?

7 A. They differ in that the second
8 form, which is the first in the binder.

9 Q. Yes.

10 A. Is considerably shorter. There
11 were more specific questions to ask in the latter study
12 than in the first. We had focussed our sights, there-
13 fore, we asked fewer questions.

14 Q. All right. And staying just for
15 the moment very briefly with page 11 of your report.
16 We have already this morning referred to the kinds of
17 assessment that Dr. Nadas made of the children on the
18 basis of the charts and it is pointed out on page 12,
19 as we discussed again this morning, the impressions
20 were clinical impressions and did not include a review
21 of forensic digoxin findings, although we are not able
22 to be sure whether Dr. Nadas in fact considered those
23 post mortem digoxin concentrations which may have been
24 found in the charts themselves.

25 A. That is correct.



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BB
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(ANSWERS BY DR. BUEHLER)

3 Q. And then as you told us
4 again this morning Dr. de Sa's objectives and so
5 on were set out as were Dr. Kauffman's in your
6 report.

7 Now when we come to page 13 we have
8 I think for the first time an identification of the
9 categories of deaths. They are set out under
10 three categories. I just want to be sure as to
11 the criteria for inclusion in each category.

12 Category A it seems has four
13 criteria, the satisfaction of any one of which will
14 qualify the death for inclusion in that category.

15 Is that so?

16 A. Yes.

17 Q. And therefore inclusion in
18 Category A may reflect a score of 3 or greater than
19 3 on the 1 to 5 digoxin scale of Dr. Kauffman, and
20 having heard his evidence I think it is fair to say
21 he regards those as fairly compelling cases of
22 digoxin intoxication related deaths, or it may
23 merely indicate that the timing of death was
24 considered to be unexpected and consistent with
25 clinical status?

26 A. Unexpected and inconsistent.



1

BB2 2 (ANSWERS BY DR. BUEHLER)

3

Q. I'm sorry, is that not what I

4

said?

5

A. You said unexpected and
6 consistent.

7

Q. I am sorry, unexpected and
8 inconsistent with clinical status, which I take it
9 is a rather less -- wrong way of putting it -- perhaps
10 a rather less compelling criteria than the 4 or 5
11 rating on the Kauffman scale as indicating some
possible digoxin involvement?

12

A. It is certainly a very
13 different type.

14

Q. Yes. Well Category A covers
15 potentially a range of levels of suspicion, if I
may put it that way --

16

A.. Yes.

17

Q. -- recognizing that
18 "suspicion" is not particularly a medical word.
19 A range of criteria of more or less compelling
nature.

20

A. Right.

21

Q. Is that fair?

22

A. Category A includes those
23 deaths where one of the three consultants used the

24

25



1

BB3² (ANSWERS BY DR. BUEHLER)

3 extreme scores available to him in assessing that
4 death.

5 Q. Well, I just want to examine
6 that for a moment. Is a notation of consistent
7 with special concern regarding digoxin intoxication
8 the extreme score on the part of the cardiologist
9 or is it rather unexpected and inconsistent with
clinical status?

10 A. They are both extreme
11 scores but --

12 Q. Okay, but in different
13 categories of his assessment?

14 A. Yes, that is correct.

15 Q. Okay. And even recognizing
16 the range of the respective compelling natures of
17 the criteria of Category A, is it fair to say there
is a considerable step down to Category B?

18 A. Yes.

19 Q. All right. And Category B
20 requires the satisfaction of two criteria, does it
not?

21 A. That is correct.

22 Q. First the time of reference,
23 onset of critical events, call for emergency

24

25



1
2 BB4 (ANSWERS BY DR. BUEHLER)

3 assistance occurred between midnight and six o'clock
4 in the morning, and the cardiologist, consulting
5 cardiologist scored the death consistent with
6 possible digoxin intoxication.

7 A. Yes.

8 Q. Now does the use of the
9 time span midnight to six o'clock as one of the
10 criteria in Category B suggest that you had come
11 to the conclusion that the time cluster that occurred
12 in so many of these deaths between midnight and
six o'clock was itself a suspicious circumstance?

13 A. Yes, and I may add to that
that long before we -- let me not add to that.

14 Q. Do I take it from that that
15 you had performed some sort of investigation as to
16 the time, the reference time in deaths in the non-
17 epidemic periods? What is so unusual about the
18 children dying between midnight and six o'clock in
19 the morning in other words? There has got to be
some base line of comparison I take it?

20 A. That is correct. These
21 criteria were developed as the investigation was in
22 progress.

23 Q. Yes.

24

25



BB5

1

2 (ANSWERS BY DR. BUEHLER)

3

4 A. And really these criteria
5 were put together as some sort of guideline for
6 evaluating potential relationships between deaths
7 and Hospital personnel.

8

9 In addition they were used in a more
10 general sense to rank deaths based on our findings,
11 the combination of findings from the consultants as
12 well as a finding that we became aware of very
13 quickly that there was an unusual clustering of
14 deaths in the early morning hours.

15

16 Q. And finally, of course, you
17 had Category C and a death fell into that if he had
18 none of the characteristics that would qualify it
19 for inclusion in either of the other categories?

20

A. Correct.

21

22 Q. Just going back to your
23 definition of "ward associated" and it is used
24 again on page 14, I would take it the one child
25 in the group with which we have interest here that would
fall into that category is the Pacsai child who
was transferred from the ward to the intensive care
unit and died there.

26

27 He would be a ward associated
28 death in your terms, would he not?

29

30



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BB6 2 (ANSWERS BY DR. BUEHLER)

3

whether or not Pacsai was one of the children who
died in the ICU, but if that is the case that would
be a ward associated death.

4

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A. I can't recall specifically

whether or not Pacsai was one of the children who
died in the ICU, but if that is the case that would
be a ward associated death.

Q. Okay. When we look at the

report as it relates to ward associated deaths after
the overall results - on page 14, halfway down the
page - there were in all 56 ward associated deaths
20 of which occurred in the non-epidemic periods
either before or after the epidemic period.

A. Yes.

Q. You say of the 36 epidemic-

period deaths there were 18 Category A deaths, 10
Category B deaths and 8 Category C deaths.

THE COMMISSIONER: There is

obviously a discrepancy - you might deal with this -
in the numbers, is there not, because Woodcock is
not included in the 36. Isn't that right?

MR. LAMEK: That is right.

Q. Although what -- was Woodcock
included in your children?

A. Woodcock died --

Q. June 30th.

A. Correct, which by definition



Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

BB7

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2

(ANSWERS BY DR. BUEHLER)

3

4

placed him - placed her, rather, in the pre-epidemic period.

5

Q. Yes.

6

THE COMMISSIONER: Who is the one extra then that we have?

7

8

9

10

MR. LAMEK: Yes, you see we have 36 including Woodcock. You perhaps include Gittens who went from the ward to the ICU and died in the ICU.

11

12

A. I'm afraid I have to look into this more carefully.

13

A. (Dr. Wallace) Yes, we do have Gittens.

14

Q. Yes, I thought so.

15

16

A. (Dr. Smith) Gittens is in the Category C.

17

18

19

Q. Yes. Gittens was not included in our group because of the interval of time between the transfer and the death.

20

21

22

23

24

25

Now in the second paragraph under the heading "Ward-associated Deaths" on page 14, you refer to the reference time, time of onset of terminal events, time of death, and you report that for 26 of 36 epidemic-period deaths, the reference



Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

1

BB8 2 (ANSWERS BY DR. BUEHLER)

3 time was between midnight and 6:00 a.m. compared
4 to 2 out of 20 for non-epidemic deaths.

5 Are you able to tell me how many
6 of those 26 who died in that period between midnight
7 and 6:00 a.m. were in Category A and how many were
in Category B?

8 A. I can't tell you that right
9 away.

10 Q. Okay.

11 A. The data is there in the
12 report to do that.

13 Q. Well, I have the information
14 but I hoped that you might have it rather more
15 conveniently collated than I have it.

16 A. Actually I don't think we
17 have the specific listing of time of onset by
18 individual cases. In the report itself I mean.

19 A. (Dr. Smith) Not in the report.

20 Q.. No, I don't think it is in
21 the report.

22 A. No, in the report itself
23 we don't have that listed.

24 Q. On page 15 referring to
25 patient characteristics you say:



Smith, Buehler
Wallace, Kusiack
dr.ex. (Lamek)

1

BB9

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(ANSWERS BY DR. BUEHLER)

3

"The median age of death was 1969 days (range of 18 to 6891 days) for the 11 pre-epidemic deaths, 42.5 days for the 36 epidemic-period deaths and 107 days for the 9 post-epidemic deaths."

4

5

6

7

8

A. Yes.

9

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Q. And the most striking feature

of that to the untrained eye, of course, is the very much lower median age for children who died in the epidemic period, ward-associated deaths in the epidemic period.

A. Yes.

Q. On the evidence that we have heard one might expect a larger number of deaths on a cardiology ward with very young children. Was the age differential in terms of median age a matter which you regarded as significant in looking at these results?

A. The way we present this data in the report does not lend itself to testing for significance.

Had we presented it as a mean age it would be possible to - mean as opposed to median -



1

BB10 2 (ANSWERS BY DR. BUEHLER)

3

it would be possible to use a statistical test to
4 define them.

5

I think simply by inspection,
6 though, there are two points that should be made.
7 There is a tremendous overlap of the ranges of
8 ages, but clearly during the epidemic period there
was a disproportionate number of younger children.

9

Q. Yes.

10

11

12

A. But the way we present it
does not lend itself immediately to a statistical
test.

13

14

15

16

We could have, for example, said
that the per cent younger than one year versus the
per cent older or there would be other ways of
presenting data that would lend itself to that kind
of test.

17

18

Q. The following paragraph too
I would like some help with it if I might.

19

20

21

Resuscitation status. You reported
5 of 36 epidemic-period deaths versus 10 of 20 non-
epidemic deaths occurred in patients who were
classified as "do not resuscitate".

22

23

24

25

If 50 per cent of the non-epidemic
deaths were in patients for whom the order "do not



Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

BB11

1

2 (ANSWERS BY DR. BUEHLER)

3

4 "resuscitate" had been written, can one infer that
5 even if the non-epidemic populations are generally
6 older than the epidemic population, and even if they
7 are less sick as you had concluded from your earlier
8 study, a higher percentage of those deaths were
9 apparently regarded as inevitable as evidenced by
10 the "do not resuscitate" notation.

11

12 Is that a fair inference to draw
13 from the relative incidences of "do not resuscitate"
14 orders?

15

16 A. There are two comparisons
17 that I think you are making simultaneously.

18

Q. Okay.

19

20 A. I am not entirely sure I
21 understand.

22

23 Q. I am not sure that I do
24 either.

25

26 Do you want me to try to do it
27 again?

28

29 A. Yes, please.

30

31 Q. You have 50 per cent of your
32 non-epidemic deaths in children for whom a "do not
33 resuscitate" order has been written.

34

35 A. Correct.

36

37



BB12

1
2 (ANSWERS BY DR. BUEHLER)

3 Q. And may one reasonably infer
4 in the first place that the presence of a "do not
5 resuscitate" order on the chart indicates that the
6 death of the child is regarded as inevitable and
7 the course is irreversible?

8 A. Yes, I think that is a
9 reasonable assumption.

10 Q. An extremely sick patient?

11 A. Yes.

12 Q. A terminally sick patient?

13 There is a lower percentage of such
14 orders written in the epidemic period with respect
15 to children who died?

16 A. That is correct.

17 Q. Therefore even if the non-
18 epidemic period children or population are older
19 and less sick than those in the epidemic period,
20 there appears to be a higher percentage of inevitable
21 death situation among those who died?

22 A. Yes, that is correct.

23 Q. Is that fair?

24 A. Yes.

25 Q. It is a rather tortuous way
of getting at it but do you understand the point I am



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

BB13

1

(ANSWERS BY DR. BUEHLER)

2

making?

3

A. Yes.

4

Q. Which would suggest, would it not, among those who died at least, a higher proportion of extremely terminally sick children in the non-epidemic period?

5

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DM/ak

1
2 (ANSWERS BY DR. BUEHLER)
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A. Among those who died?

Q. Yes.

A. Yes, that is right.

Q. And indeed of the five do not resuscitate patients who died during the epidemic period Floryn was 19 years old; Heyworth was 11 years old; Murphy was 16 years old, and indeed there were only two of those five, Leith and Perreault who were two months and three weeks respectively, only two patients in the epidemic period who were infants in respect of whom do not resuscitate orders were written. Does that comply with your understanding of those facts?

A. Yes.

Q. Does it seem therefore that the younger population, if there was a younger population in the epidemic period did not seem to be producing, among those who died, a higher number of inevitable deaths, they had a relatively small number of inevitable deaths among those who died, did they not, as evidenced by the DNR orders?

A. May I check something in my notes?

Q. Yes, of course.



C2

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2

(ANSWERS BY DR. BUEHLER)

3

A. I can break that information -
broken down, this information is not in the report
but it is information that we have.

6

Q. Just before you do that,
Doctor, I should be clearer of course. The presence
of a DNR order on a chart I guess is a function of
two things; one, an assessment of the absolute
inevitability of the child's death, but also the
parents' consent to that order is it not, you are
not likely to find a DNR order unless you have been
in consultation and agreement with the parents,
is that fair?

14

A. Dr. Smith, I don't think we --

15

Q. That is the evidence that we
have heard with respect to the Hospital in any
event. So it is not standing alone an indication
that these were the only inevitably doomed children?
I'm sorry, could we have your information please?

19

THE COMMISSIONER: I'm not sure
that information of yours, that statement of yours
is correct, standing alone it is --

22

MR. LAMEK: It is, that's right.

23

THE COMMISSIONER: It is but there
may be others.

24

25



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MR. LAMEK: There may be others

6

who inevitably were going to die irreversibly but
for whom the parents did not consent, that is
absolutely right, sir.

7

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DR. BUEHLER: If you look at

children who are under a year of age, or greater
than five years of age, or you can break it down by
under or over a year of age, most of the older
children are the ones who are more likely, regardless
of epidemic versus non-epidemic, to be classified
do not resuscitate.

MR. LAMEK: Q. That in fact is

what is borne out from that very small sample of
five in the epidemic period, three were over the
age of 11 or more years old, and only two were
small children.

(ANSWERS BY DR. BUEHLER)

A. Yes.

Q. You also considered, the

middle of page 15:

"Digoxin therapy and other medications."

Can you tell me please why you were
interested in determining the time of dose of digoxin
prior to death if the child were on digoxin?

A. One of the questions



C4

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(ANSWERS BY DR. BUEHLER)

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that we specifically asked Dr. Kauffman to give us advice on was if the child died as a result of an overdose of digoxin what is, number one, the longest time between the administration of the intravenous dose and death that you might expect.

8

Q. Yes.

9

10

11

A. And his advice to us was that it could occur up to four hours later, much more likely to have occurred sooner but it conceivably could.

12

Q. You were asking at the outside?

13

14

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A. The outside, yes. Similarly we asked if an overdose were administered by the oral route what is the outside time at which it could result in death. We looked at medications, a number of medications given during these various intervals, four hours, eight hours, to see whether or not children who died during the epidemic period were more likely to have been given medications and therefore were they more likely to be subject to an accidental medication error.

22

23

24

25

Similarly, we wondered if they were more likely to be given digoxin specifically, and therefore more likely to be subject to accidental



Smith, Buehler,
Wallace, Kusiak,
dr.ex. (Lamek)

CC5

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(ANSWERS BY DR. BUEHLER)

3

digoxin error.

4

Q. And on the results that you produced, was it your conclusion that in terms of the time of lost administration of digoxin, and indeed any other drug, in children who died in the epidemic period as opposed to those who died at other times, there did not appear to be any greater occasion for medication error shortly before death in the epidemic period than at any other time?

11

A. That is correct. There was a converse finding if you may in that children who died during the epidemic period were actually less likely to have been given a dose of digoxin that was prescribed and documented in the Hospital chart within four hours prior to their death when compared to the non-epidemic period.

17

Q. You canvassed too, pre-mortem digoxin levels; other measures such as IV lines; nasal gastric tube feeding and that sort of thing. You report under "Other Therapeutic Measures":

21

"Within the epidemic - period group all 18 Category A deaths, 9 of 10 Category B deaths, and 4 of 8 Category C patients had an intravenous line."

24

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(ANSWERS BY DR. BUEHLER)

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I don't see at a quick look the information as to the non-epidemic, oh yes, 45 per cent of the non-epidemic deaths had an IV line at the reference time. You had a total of 18, 27, 31 of 36 of the epidemic period children had an IV line in place.

9

THE COMMISSIONER: Have we the data as to --

10

MR. LAMEK: I am sorry.

11

12

THE COMMISSIONER: Which of these children was the 31 that you had the IV line.

13

14

MR. LAMEK: We know they were all of the Category A18.

15

THE COMMISSIONER: Yes.

16

17

MR. LAMEK: Q. Can you tell me which of the Category B deaths did not have an IV line in place?

18

A. (Dr. Wallace) I believe Lutes.

19

20

Q. Lutes, thank you. And in the Category C patients?

21

A. I can't really tell.

22

Q. You can't tell?

23

A. Right.

24

Q. At the very bottom of page 15

25



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(ANSWERS BY DR. BUEHLER)

3

4

over onto page 16 we come to the "Cardiologists
Scoring". Can you help me, is it more useful to
look at the text or at the tables on this?

6

7

A. I think it might be more
useful to look at the tables.

8

9

10

11

Q. Table 7 is the long table that
continues over 2 pages. It is a close run thing
but I think I am marginally better at words than I
am at numbers, so I will look at the text and flip
to the table if I may.

12

13

The finding is stated at the top of
page 16:

14

15

16

17

18

"For all categories, there were no
significant differences in the
distribution of scores between the
pre and post-epidemic period."

Is that all categories, all subdivisions of cardiology
deaths?

19

A. Yes.

20

21

22

23

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Q. And indeed if I understand
the numbers correctly, and perhaps you can demonstrate
it more clearly from the table, a lower percentage
of the epidemic deaths than of the non-epidemic
deaths was scored as critical on admission, and as



Smith, Buehler,
Wallace, Kusiak,
dr.ex. (Lamek)

CC8

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(ANSWERS BY MR. BUEHLER)

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4

having a poor prognosis on admission, do I have that
correctly?

5

6

A. Yes, that is correct, but I
think it is important to note that --

7

8

Q. We are now looking at Table 7?

A. Yes, I am looking at Table 7.

For the status on admission of the sub-total of
29 epidemic deaths, 12 were in critical condition,
60 per cent compared to 9 of the 36, 25 per cent;
so approximately two times as many non-epidemic
patients were in critical condition at the time of
admission compared to epidemic patients, 60 per cent
versus 25 per cent.

15

16

Q. And these are of those patients
who died?

A. That is correct.

17

18

Q. In the non-epidemic and then
in the epidemic periods?

19

A. Correct.

20

21

Q. And is that difference of
statistical significance?

22

A. Yes, it is.

23

24

Q. Insofar as prognosis on
admission is concerned, the difference in terms of

25



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(ANSWERS BY DR. BUEHLER)

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percentage of those having poor prognosis on admission is not so dramatic, but is nevertheless larger in the case of the non-epidemic period deaths than in the case of the epidemic period deaths.

7

8

9

A. It is 65 per cent versus 50 per cent, which is not a significant difference, it is a larger value but not statistically significant.

10

11

Q. But not statistically significant?

12

A. Yes.

13

14

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Q. Does it follow from that at least that even if your conclusions stated this morning were correct, that the population on the cardiology wards in the epidemic period was generally younger and more severely ill than at other times, it does not appear that the children who died in the epidemic period were either more severely ill at admission, or had a poorer prognosis on admission?

A. That is correct.

Q. And indeed they were less

severely ill and had generally better prognosis than those who died in the non-epidemic periods?

A. I would place more emphasis



Smith, Buehler,
Wallace, Kusiak,
dr.ex. (Lamek)

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(ANSWERS BY DR. BUEHLER)

3

on the severity rather than the prognosis.

4

Q. Because of the statistical significance of that difference as opposed to the prognosis figures?

5

A. The difference between 25 per cent and 60 per cent I think is a more important difference than the difference between 50 per cent and 65 per cent.

6

7

Q. It is equally true as I understand your report that a higher percentage of the epidemic deaths than of the non-epidemic deaths was scored as unexpected and inconsistent with clinical status, scored as consistent with special concern with respect to digoxin intoxication, and indeed was scored as requiring a high level of care in the reference time?

8

A. Let me review those one at a time.

9

Q. Okay, one at a time.

10

A. Concerning the time of death --

11

Q. We are now looking at the second page of Table 7.

12

A. The second page at the top.

13

Q. Right.

14

15



Smith, Buehler,
Wallace, Kusiak,
dr.ex. (Lamek)

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2

(ANSWERS BY MR. BUEHLER)

3

4 A. There was one patient, there
5 was one non-epidemic patient who had unexpected and
6 inconsistent timing of death according to Dr. Nadas'
7 clinical impression.

8

Q. Yes.

9

10 A. In other words, 5 per cent,
11 one at 20, compared to 6 of 36 who died during the
12 epidemic period, or 16 per cent, so roughly three
13 times as many patients had that score. That
14 difference however, breaking the table in that way
15 was not statistically significant.

16

17

Q. Notwithstanding a factor of
three at work?

18

19

A. Yes, the numbers are very
small.

20

21

22

23

24

25

Q. Looking at the next table
related to possible - mode of death related to
possible digoxin intoxication, again emphasizing
these are Dr. Nadas' clinical impressions; one of
20 or 5 per cent of non-epidemic patients have
that score consistent with special concern, that
extreme score compared to 11 of 36, or approximately
30 per cent of epidemic patients, so roughly six
times as many patients during the epidemic period.



Smith, Buehler,
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dr.ex. (Lamek)

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312 THE COMMISSIONER: Was this one
3 Woodcock?

4

5 DR. BUEHLER: Yes, in both cases
that one patient was Woodcock.

6

7

MR. LAMEK: Q. Is that a statistically significant difference?

8

A. Yes, that is.

9 Q. Now in light of what you said
10 this morning about the higher level of care desired
11 and that assessment being placed upon clinicians
12 in Dr. Nadas' own hospital, the next comparison
13 may or may not be of some significance, but I think we
14 referred to it this morning, did we not?

15 (ANSWERS BY DR. BUEHLER)

16

A. Yes.

17

18

19

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1
23jan84 2 (ANSWERS BY DR. BUEHLER)
DD
BMCrc 3

4 Q. That although 12 of 36 of the
5 non-epidemic cases of Dr. Nadas' cases where a higher
6 level of care was desired, similarly, 30 per cent
7 of the non-epidemic deaths were similarly scored
8 by Dr. Nadas?

9 A. That is correct.

10 Q. Okay. Just one question if
11 I may. Could we turn perhaps to Woodcock in the
12 Nadas reports. It is the very last report in the
13 binder, page 109.

14 You identify Woodcock as being the
15 one non-epidemic death which Dr. Nadas scored as
16 being consistent with special concern with respect
17 to digoxin intoxication.

18 Now, I agree in some of these forms
19 Dr. Nadas has written in that extra third category
20 under heading C. This is a case where he does not
21 seem to - he has got a plus sign.

22 A. That's what that means.

23 Q. That's what that means?

24 A. Yes.

25 Q. Okay, it is consistent plus
means with special concern?

A. Correct.



DD2

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(ANSWERS BY DR. BUEHLER)

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THE COMMISSIONER: Is there any relation between his answer to B and his answer to C? I know he is not here but the fact that he puts it unexpected, inconsistent with clinical status, does that help to bring about the special concern about digoxin? How did he work that out? How did he work out the special concern? Was that independent of whether it was unexpected and inconsistent with the clinical status?

DR. BUEHLER: Yes. They are two separate questions.

THE COMMISSIONER: I know they are. But I am just wondering if his answer to the first question influenced him on his answer to the second. Did anybody ever discuss that with him?

DR. BUEHLER: Let me try to give an example.

THE COMMISSIONER: We can solve the problem I suppose by looking to see if there are any --

DR. BUEHLER: Yes.

THE COMMISSIONER: If we look at, I don't know, there is always -- Oh, here's one which is 02007, page 98, and that would be Turner.



1

DD3 2 (ANSWERS BY DR. BUEHLER)

3

It seems to be unexpected but consistent with the
4 clinical status and yet got a consistent plus on
5 digoxin. Page 98.

6

DR. BUEHLER: Correct. If you look
7 at the table in the Appendix there are some children
8 that had the extreme score for timing and some that
9 had the extreme score for consistency with digoxin
intoxication and some had both.

10

11

THE COMMISSIONER: What table was
that, Doctor?

12

DR. SMITH: Appendix 2.

13

DR. BUEHLER: Appendix 2.

14

DR. SMITH: I'm sorry, Appendix 3.

15

THE COMMISSIONER: Appendix 2 is
the...

16

DR. WALLACE: Appendix 3.

17

DR. BUEHLER: Appendix 3.

18

THE COMMISSIONER: Appendix 3.

19

DR. BUEHLER: Approximately page 74
through 76.

20

THE COMMISSIONER: There are certainly
some cases. I see. All right. Thank you.

22

23

MR. LAMEK: Q. Now, is there
anything else that we should be looking at particularly

24

25



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DD4 2

(ANSWERS BY DR. BUEHLER)

3 in Table 7 that we regard as significant in going
4 to the conclusions of your report?

5 A. I think one point that should
6 be emphasized is the potential for misunderstanding
7 these scores.

8 Q. Yes.

9 A. And when we look at, for
10 example, the mode of death which is the middle
11 table on the second page of page 7, if you look at
12 the subtotal for non-epidemic deaths there were
13 10 children who died during the non-epidemic
14 periods who had a mode of death that to Dr. Nadas
15 appeared to be consistent with digoxin intoxication.
16 That tells us that even during the period when
17 there appears to be relatively little or no concern
18 about deaths being due to possible digoxin overdose,
19 half of the patients had a mode of death that was
20 clinically consistent with digoxin overdose. That
21 tells us that at least using the scoring that Dr.
22 Nadas did the clinical pattern of death, particularly
23 as it relates to possible digoxin overdose, is not
24 specific. I think that is an important point.

25 Q. Understood. But, Doctor, is
26 that a fair way of putting it because you have
27



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DD5 2 (ANSWERS BY DR. BUEHLER)

3 focused on the middle column which is consistent
4 with those in the right-hand column too which are also
5 consistent but with special concerns?

6 A. That's right.

7 Q. And is it not fairer to say
8 that Dr. Nadas regarded 11 deaths as consistent
9 with digoxin overdose; one of them having special
10 concern attached to it but considered 30 in the
11 epidemic period to be consistent with digoxin
12 intoxication, 11 of those having special concerns
13 attached to them?

14 A. That is quite correct.

15 Q. And therefore, although I
16 accept your point entirely of course that the mode
17 of dying with digoxin intoxication is not specific,
18 the fact is that Dr. Nadas discovered 11 such deaths
19 in the non-epidemic period which he considered to
20 have in a mode consistent with digoxin intoxication
21 but 30 such deaths in the epidemic period. Is that
22 fair?

23 A. 11 of the 20 versus 30 of
24 36?

25 Q. Yes.

A. Yes, that is an important



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

DD6

1

2 (ANSWERS BY DR. BUEHLER)

3

difference that distinguishes deaths during the
epidemic period, you are quite correct.

4

Q. You see, we have heard from
highly respected people whose opinions are obviously
respected that there is no particular set of
symptoms which characterize death from digoxin
overdose or specific to death from digoxin overdose.
Indeed, we have heard cardiologists say, look,
virtually all of these 36 deaths are so consistent.
If I take anything from this may I take this that
even though that be so half of the deaths that
Dr. Nadas looked at in the non-epidemic period he
considered to be - almost half - inconsistent with
the mode of death that he would expect in the case
of digoxin intoxication but only 15 per cent, 6 out
of 36 in the epidemic period did he regard in that
light. Is that fair?

5

A. 16.7, correct.

6

Q. All right. I was never good
at translating ~~fixed~~ into percentages.

7

You then report upon the pathologist's
consultation, page 16, and the pharmacologist's
consultation and indeed we have heard from Dr.
Kauffman himself with respect to his own results.

8

9



DD7

1
2 (ANSWERS BY DR. BUEHLER)

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25
On page 17 you dealt with operating room associated deaths. I am not quite sure why you did that study but perhaps you can help us. What was the purpose in that study?

A. The purpose of this part of the study was to determine whether or not differences between deaths that were ward associated during the epidemic period were also -- let me rephrase that. The purpose was to determine whether there were also differences during the epidemic period and the characteristics of OR-associated deaths.

Q. Yes.

A. And whether or not the pattern of the OR-associated deaths resembled those of ward-associated deaths.

Q. And you considered a variety of factors: The place from which the child went to surgery, features of the patients, procedures, prognosis, scores, and your conclusion was what?

A. Well, this part of the study was not as important I think as other parts of the study. One of the interesting things we did observe however dealt with the location prior to surgery, whereas, for epidemic-period deaths there was a



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

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2 DD8 (ANSWERS BY DR. BUEHLER)

3 preponderance of deaths in children who were on
4 Ward 4A. During the epidemic period, 10 of - reading
5 from the middle sentence of that paragraph:

6 "For epidemic-period deaths 10 of
7 28 or 35.7% were on Ward 4A and
8 16 or 57.1% on Ward 4B."

9 So that for children who were
10 admitted to the Hospital who passed through a
11 cardiology ward and later died either in the operating
12 room or in the ICU --

13 Q. In the ICU after the OR?

14 A. Yes.

15 Q. Yes.

16 A. There was not an apparent
17 disproportion of those children from Ward 4A as
18 we saw with ward-associated deaths. I think the
19 second characteristic that distinguishes the
20 pattern of deaths in OR-associated deaths deals
21 with patient features and, that is, that the
22 median age of death for pre-epidemic patients was
23 146 days, for epidemic period patients 696 days
24 and for post-epidemic period it was 569 days. In
25 other words the children who went on to die either
in the OR, after the OR during the epidemic period



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

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DD9 2 (ANSWERS BY DR. BUEHLER)

3 were older, which is again different from the
4 pattern we observed for ward-associated deaths.

5 Q. You come on page 18 to
6 another area of investigation, that of Possible
7 Digoxin-related Morbid Events.

8 A. Yes.

9 Q. I take it you are now looking
10 for episodes during the life of children where they
11 appeared to be suffering from a measure of digoxin
12 intoxication short of death?

13 A. Correct.

14 Q. Is that what we are looking
15 for here?

16 (ANSWERS BY DR. WALLACE)

17 A. Yes, that is correct.

18 Q. And what was the purpose
19 in looking for those incidents?

20 A. This part of the study was
21 done very early on in our investigation. It is
22 being reported here slightly out of sequence.
23 Because digoxin was a feature in some of these
24 deaths, early on we reviewed the digoxin log books
25 because all children who are on digoxin are monitored.
We looked at the log books starting at the time of



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

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DD10

2

(ANSWERS BY DR. WALLACE)

3

4

the epidemic period to see in fact if any of these children had been having high levels of digoxin throughout their stay at the Hospital. We in fact found this not to be the case.

5

6

Q. Why were you interested in knowing that though?

7

8

A. We had asked ourselves if these children might have been exposed to continuing higher doses of digoxin than were prescribed for them.

9

10

11

Q. And there didn't appear to be any change in the appearance of elevated digoxin levels produced by the therapeutic monitoring program?

12

13

14

15

16

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18

19

A. That is correct. The levels sent from Wards 4A and Ward 4B did not differ from the specimens sent from the ICU or the NICU, which are the other two wards which would mainly use digoxin.

20

21

22

23

24

25

Q. We come then to what you call the Death-Roommate Study, the purpose for which the first form in the binder, the first numbered form in the binder was prepared.

THE COMMISSIONER: I have the



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

1

DD11 2 (ANSWERS BY DR. WALLACE)

3

advantage of seeing the clock. It is two minutes
4 to our usual hour. Do you want to take a break
now?

5

6 MR. LAMEK: It is an excellent time
to take a break, thank you, sir.

7

8 THE COMMISSIONER: Yes, all right,
fifteen minutes.

9

--- recess.

10

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EMT.jc
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--- On resuming:

3

THE COMMISSIONER: Yes, Mr. Lamek?

4

MR. LAMEK: Thank you, sir.

5

6

Q. We have arrived I think at page
18 of the report, the heading VII, "Death Roommate
Study".

7

Again I would ask you to help me,
please, if you would. What was the purpose in
conducting the death roommate study?

10

(ANSWERS BY DR. SMITH)

11

12

13

A. The purpose in this study was
to try to determine what differences existed between
the children in a particular room that made them
die as compared to the surviving roommates.

14

15

16

We wanted to find out if any
particular process, any selection occurred to make
one child a death as compared to the other.

17

18

19

Q. Okay. Was this study done
reasonably late in the investigation? Where did it
fit into the overall work?

20

21

A. This study was started about
half way through our - the fall - half way through
the investigation.

22

23

Q. Had you by this time received
Dr. Nadas' scoring of the patients?

24

25



EE.2

1

2 (ANSWERS BY DR. SMITH)

3 A. I can't recall. Had we? We had.
4 I am told that we had.

5 Q. All right. That is Dr. Buehler's
6 recollection in any event.

7 THE COMMISSIONER: Also Dr. Wallace.
8 I saw all their nods.

9 MR. LAMEK: You got a casting vote,
10 Dr. Wallace.

11 Q. When you say "selection" are
12 you suggesting conscious selection of one patient
13 rather than another? Was that what was in your mind?

14 A. That was a question we had, yes.
15 We didn't write that into the report.

16 Q. No.

17 A. But it was certainly a question
18 we had.

19 Q. Is it fair to infer from that,
20 Dr. Smith, by the time you embarked upon the death
21 roommate study you were at least entertaining the
22 possibility that the epidemic was wholly or in part
23 attributable to the acts of some person?

24 A. Yes. I would say that by this
25 time that was a consideration.

26 Q. I take it because having
27 canvassed a number of other features that might have



EE.3

1

2 (ANSWERS BY DR. SMITH)

3 provided an explanation you had drawn a blank on
4 each of the investigations you had undertaken?

5 A. That is right.

6 DR. BUEHLER: May I add a subscript
7 to that?

8 MR. LAMEK: Certainly.

9 DR. BUEHLER: Certainly by that time
10 we had finished many of the different analyses that
we had undertaken.

11 I think by the very nature of the
12 history of the event itself that was a concern.
13 Certainly something that anyone approaching this
14 issue would consider among possible explanations
for this.

15 MR. LAMEK: Q. All right. And
16 considering that possibility you embarked upon a
17 study to see if there was some, as I think you said,
18 Dr. Smith, pattern of selection of one child as
19 opposed to those in the same room as that child at
the time he died?

20 A. That is correct.

21 Q. In order to arrive at that
22 comparison or study you appear to have identified
23 a whole host of characteristics to see if they were

24

25



EE.4

1

2 (ANSWERS BY DR. SMITH)

3 in common or distinguishing features between the child
4 who died and his surviving roommates.

5 Are these many of the features and
6 elements which were recorded in the general overall
7 questionnaire that we have looked at?

8 A. That is correct. Any feature
9 that is mentioned here would have been included as a
10 question in the questionnaire for both the cases and
the controls.

11 Q. All right. Age, race, sex,
12 place of residence, diagnosis, condition, whether there
13 had been a catheterization; if so, when; surgery,
14 medications, presence or absence of I.V. lines. A
15 whole host of factors that you mention in the long
16 paragraph at the bottom of page 18?

17 A. That is correct, yes.

18 Q. And having considered all those
19 variables did you conclude that there was any
20 discernible pattern of selection as between the
21 children who died and their surviving roommates?

22 A. I would like to refer to page 19.

23 Q. Yes.

24 A. "Nursing time required". These
25 are the positive findings. Basically there were no



EE.5

1

2 (ANSWERS BY DR. SMITH)

3 differences in all of the categories listed in the
4 second paragraph on page 19.

5 However, the patients who died required
6 more nursing care than their roommates. That is
7 their NARvel score was higher overall.

8 Q. That is at the time of their
9 death?

10 A. At the time of their death they
11 required more nursing care, yes.

12 Q. Does that suggest that at the
13 time of their death they tended to be sicker than
14 their surviving roommates?

15 A. Yes. At the reference time.

16 Q. Yes.

17 A. They were sicker than their
18 roommates in general, yes.

19 THE COMMISSIONER: As I trust before
20 the reference time?

21 DR. SMITH: This is the closest
22 NARvel score that they were given, closest to the
23 reference time.

24 THE COMMISSIONER: Yes.

25 DR. SMITH: Because the NARvel scores
26 occur only once a day.



EE.6

1

2 (ANSWERS BY DR. SMITH)

3 MR. LAMEK: Q. Yes.

4 A. So this would have been the
5 closest NARvel score for that patient.

6 Q. I am not sure that I understand
7 paragraph numbered 2 under B on page 19. You say:

8 "All of the following patient-care
9 variables were associated with death:".

10 Does that mean that these various elements occurred
11 in one or more deaths?

12 A. That they were - this means that
13 the children who died were more likely to be younger,
14 have had a cardiac catheterization, have been on
15 oxygen therapy, have had an NPO feeding status,
et cetera, than their roommate at the time, at the
reference time.

16 Q. It is clearly my failure to
17 comprehend what you are saying to me, but I see that
18 two of those characteristics, for example, are NPO
19 feeding status which you define as no oral, gastric
or duodenal feeding. The next item is tube feeding.

20 Now to me those two tend to be
21 contradictory.

22 A. (Dr. Buehler): If you look at the
23 words that immediately follow the parentheses for

24

25



EE.7

1

2 (ANSWERS BY DR. BUEHLER)

3

4 tube feedings, "for those patients who were receiving
5 feedings", so that even though in general the children
6 who died were less likely to be receiving feedings --

7

8 Q. If they were they were likely
9 to be on tube feedings?

10

11 A. They were more likely to be
12 being fed by tube.

13

Q. All right. Thank you.

14

15 " ... and the presence of a pre
16 mortem digoxin level greater than 2
17 nanograms per millilitre in the most
18 recent specimen tested for those
19 patients who had measurements taken."

20

21 (ANSWERS BY DR. SMITH)

22

23 A. That is right.

24

25 Q. And then you issue a caveat with
respect to the significance of those observations
because you say:

" ... because all of these variables
may be associated with severity of
illness and because severity could
not be completely controlled in
making comparisons".

A. That is correct.

26

27



EE.8

1

2 (ANSWERS BY DR. SMITH)

3 Q. Are you suggesting that it may
4 be those patients who exhibit those characteristics
5 who are also those who on the NARvel scoring most
6 closely proximate to the reference time were thought
7 to be most in need of nursing care?

8 A. That is correct.

9 Q. They may not be two aspects of
10 the same thing?

11 A. Yes, but it is important to
12 point out that the NARvel score is not strictly
13 speaking an accurate --

14 Q. No.

15 A. -- assessment of severity.

16 Q. It may be an indicator only?

17 A. It may be an estimation --

18 Q. Yes.

19 A. An estimation of severity.

20 Q. Were you able to draw any
21 real or firm conclusions from this death roommate
22 study? Was it of any significant assistance to you
23 in solving this conundrum?

24 A. Well, in the end it did not
25 prove to be a very helpful study, but we had no way --

Q. You didn't know that until you
had done it?



EE.9

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2

(ANSWERS BY DR. SMITH)

3

A. Until we had embarked upon it.

4

Q. Fair enough. And so you come in
Item No. 8 on page 19 to association of deaths with
hospital personnel.

5

6

Can you tell me, please, why you
7 embarked upon that exercise?

8

(ANSWERS BY DR. BUEHLER)

9

A. This was an issue that clearly
10 had been raised before we arrived.

11

Q. Yes.

12

A. We felt that it was a compelling
13 issue for us to address and I think we can give you
14 an analogy of attempting to investigate a different
type of outbreak in a hospital.

15

16 For example, an outbreak of infectious
disease where in such an investigation it would, by
17 routine, be considered an integral part of the
18 investigation to determine whether or not a particular
member of the physician staff or nursing staff or
19 other ancillary staff might, for example, be a carrier
20 of an infectious organism themselves.

21

Q. Yes.

22

A. Clearly we were concerned about
23 the possibility of overdoses of digoxin, and we felt

24

25



EE.10

1

2 (ANSWERS BY DR. BUEHLER)

3 that it was necessary to try and determine whether
4 or not there was any association between individual
5 members of the hospital staff and certain deaths .

6 Q. And I take it that this was not
7 an exercise which lay peculiarly within the province
8 of epidemiologists. Having identified the deaths,
9 particularly with the assistance of Dr. Nadas, having
10 identified those to which some element of suspicion
11 was thought to attach, I take it you did not need to
12 be an epidemiologist to compare available information
13 as to whereabouts of hospital personnel with those
14 deaths?

15 A. Well, I think we approached it
16 from an epidemiologic point of view.

17 Q. Yes.

18 A. But you are correct. I think
19 also the type of investigation we did clearly is
20 different from the type of investigation that, for
21 example, a police investigator might do.

22 Q. Yes.

23 A. I think as we go through this
24 it will be important to keep that in mind.

25 Q. As I understand it you attempted
26 to establish where hospital personnel of all kind may



EE.11

1

2 (ANSWERS BY DR. BUEHLER)

3 have been at particular times. Ideally you would have
4 loved to have had I take it a reliable timetable of
5 everybody's movements for the nine-month period?

6 A. That would clearly be ideal.

7 Q. Yes. And clearly the reality
8 fell a good deal short of that?

9 A. Correct.

10 Q. You report on page 20 with
11 respect to physician assignments:

12 " ... they were determined from
13 monthly rosters and nightly call
14 schedules for residents, fellows and
15 cardiology staff physicians. There
16 was no permanent record of impromptu
17 schedule changes made by physicians."

18 Was that a matter that perhaps you
19 could have remedied by inquiry? Could you not have
20 started with the call schedules to determine who
21 was supposed to be where at particular times with
22 respect to doctors, and then had you noticed an
23 association between one or more doctors and deaths
24 made some inquiries as to whether in fact the people
25 were actually where they were scheduled to be? Could
you have done that?



EE.12

1

2 (ANSWERS BY DR. BUEHLER)

3 A. I think inquiries of that type
4 were clearly beyond the scope of what we could have
5 done.

(2)

6 Q. All right. Did it really come
7 to this, that the only group in the hospital about
8 whom you had relatively complete and reliable infor-
9 mation as to the whereabouts was the nursing group?

10

A. That is correct.

11

Q. Right. What other groups or
12 persons did you attempt to establish such death about?
13 We have referred to doctors. Were there any other
groups or categories?

14

A. May I deal with that first?

15

Q. Yes, of course.

16

A. We felt that - I think it is
important to refer back to the early part of the text.

17

Q. Yes.

18

A. Where we in our meetings with
19 hospital authorities, physicians, different persons
20 who are familiar with the types of people who were
21 on duty, we became aware that most of the ancillary
22 personnel of the hospital such as physical therapists,
respiratory therapists, occupational therapists,
23 et cetera, and ward clerks go off duty at approximately

24

25



EE.13

1

2 (ANSWERS BY DR. BUEHLER)

3 10 or 12 o'clock - I'm sorry, between 10 and 11
4 o'clock in the evening.

5 Q. Yes.

6 A. In general, given the timing of
7 the problem that we were looking at, and given the
8 range of times in which overdoses of digoxin may have
9 been given as suggested to us by Dr. Kauffman, then
10 the two groups - those hospital employees on whom
11 we should focus the greatest attention should be the
12 physicians and the nurses because they are there
13 around the clock. There are others who visit the
wards after hours.

14 For example, there is the nightly
15 collection of garbage around midnight or in the
16 vicinity of that time. There was a courier who
17 collected the NARvel scores and census information
18 at approximately midnight, but we focussed most
carefully on physicians and nurses.

19 We looked to a lesser extent at other
20 hospital employees, mainly during the latter three
21 months of the epidemic period when there was - when
22 some of these deaths occurred.

23 Q. Was it part of your thinking
24 in narrowing your focus to doctors and nurses that
25



EE.14

1

2 (ANSWERS BY DR. BUEHLER)

3 they were the two groups who would be least likely
4 to arouse comment if seen in a child's room? Was
5 that part of the narrowing process?

6

7

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Smith, Buehler
Wallace, Kusiak
dr.ex. (Lamek)

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23jan84 2 (ANSWERS BY DR. BUEHLER)

FF
DMrc

A. That was the concern in the realm of possibility that we had but -- yes, that is correct, sir.

Q. When you come to the results -- I'm sorry, before you get to the results, the second full paragraph on page 20 it says:

"Nursing assignments were determined from personnel records maintained by the Head Nurses on Wards 4A/B and from the nursing assignment workbooks."

Were those personnel records or payroll sheets or something that go to make up payroll sheets?

A. (Dr. Smith) They were the final correction that went to Payroll, so that someone might be entered as being there but if they didn't show up they would be crossed out, so they were the handwritten corrected sheets that were used by Payroll.

Q. Sort of clocking on and clocking off information?

A. (Dr. Smith) Yes, that is correct.



1 (ANSERWS BY DR. BUEHLER)

FF2 2 Q. You say:

3 "This task was performed by a Ward
4A team leader who was familiar
5 with these documents. (She was
6 recommended by the nursing administra-
7 tion...)"

8 Not a member of the Trayner team.

9 "A nursing calendar was constructed
10 to define individual nurse person-
11 hours on the cardiology wards
12 throughout the epidemic period."

13 Can you tell me a bit more about that
14 nursing calendar, what was it? Was it a huge
15 timetable of who was there and when?

16 A. Yes. We broke down the
17 entire epidemic period into one half hour intervals
18 and we attempted to identify over that entire nine-
19 month period who was there and who was not on
20 Ward 4A and 4B.

21 Q. Who actually constructed that
22 nursing calendar?

23 A. The nursing calendar was
24 constructed by - do you want the name of the
25 person?

26 Q. Yes, please.



1

FF3

2

(ANSWERS BY DR. BUEHLER)

3

A. Miss Cathy Shilton.

4

Q. Yes. And what check was
made of the accuracy of her work?

5

THE COMMISSIONER: I'm sorry, was
she on your staff?

6

MR. LAMEK: No she is a nurse at
the Hospital.

7

THE COMMISSIONER: Cathy what?

8

DR. BUEHLER: Shilton.

9

DR. SMITH: Shilton.

10

THE COMMISSIONER: Yes. Thank you.

11

(ANSWERS BY DR. SMITH)

12

13

A. We did several checks of
her transfer of the information into single 24-hour
sheets that she captured from the workbooks and from
the payroll books. These data were then translated
into a questionnaire that was suitable for entry
into a computer, so that we could deal with the data,
that we could handle the data in a computer; we
further checked any inconsistencies in the data when
we had the computer printout back with the original
data and found some errors, we made further
corrections, had several runs of that which our
statistician can address, and any time that there was

14

15



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

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FF4

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(ANSWERS BY DR. SMITH)

3

4

a discrepancy found we went back to original data
and ensured that in fact appropriate entries had
been made.

5

6

MR. LAMEK: Q. When we come to the
results set out at the bottom of page 20 you first
say:

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"There was no association observed
between any physician and deaths
during the epidemic period and no
association between deaths and
housekeeping personnel or ward
clerks."

Is there some intended significance
to the slight change in the wording as it relates
to physicians and then as it relates to housekeeping
personnel and ward clerks? You say:

"There was no association observed
between any physician and deaths..."

and then:

"...and no association between deaths
and housekeeping personnel or ward
clerks."

(ANSWERS BY DR. BUEHLER)

A. No, there is no significance.



Smith, Buehler
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dr.ex. (Lamek)

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FF5 2 (ANSWERS BY DR. BUEHLER)

3

not able to see any association because you didn't
have the information?

5

6 A. Well, for physicians, in
7 general the physicians rotated on and off the
8 service at approximately four to six week intervals.

9

Q. Yes.

10

11 A. If you look at a nine-month
12 period using the information that we had concerning
13 when physicians were there based on the cost
14 schedule we didn't see any pattern of association,
15 consistent association, between individuals and
16 deaths.

17

18 Q. And when you refer to
19 physicians I take it you are including house staff
20 like residents?

21

A. Residents, Fellows.

22

Q. And staff physicians?

23

A. Yes.

24

Q. You say:

25

"...there were 280 nurses who
worked on Wards 4A/4B during the
peidemic period."

That is the grand total of everybody



FF6

1
2 (ANSWERS BY DR. BUEHLER)

3 who came onto that ward in a nursing capacity in
4 that period I take it?

5 A. That is right.

6 Q. And of those 280, 46 of them
7 were on duty at the reference time for one or more
8 ward-associated deaths. 57 were on duty within
9 four hours preceding the onset of terminal events
10 for one or more deaths, and you refer to Table 10
and Table 9, and we will look at those in a moment.

11 "The relative risk for the onset
12 of a terminal event occurring within
13 four hours of a nurse's presence on
14 the ward is shown in Table 11 for
15 the 12 nurses associated with the
16 greatest number of Category A
17 deaths. There are no differences
18 between these risk estimates and
19 those for events occurring during
20 or within eight hours of a nurse's
21 presence on the ward; the latter
22 data are therefore not shown. For
23 the four cases where the consultant
pharmacologist estimated an approximate
24 time of digoxin administration,

25



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FF7 2 (ANSWERS BY DR. BUEHLER)

3

nurses on duty at those times are
shown in Table 12."

4

Perhaps therefore we should look at
Tables 9 to 12; I seek please your clarification
or explanation of them as you think necessary.

5

6 A. Table 9 shows us the
7 frequency of nurses on duty at the time of onset
8 of terminal events for ward-associated deaths and
9 during the epidemic period. There were 18 Category A
10 deaths, 10 Category B deaths and 8 Category C
11 deaths in a total of 36 deaths. The nurses are
12 ranked in descending order, in general, and you
13 can see that there was one nurse who was on duty
14 at the time of terminal onset events for 18 of
15 18 Category A deaths, for 10 of 10 Category B
16 deaths and for 4 of 8 Category C deaths. And
17 similarly you can read down the line.

18 There was a nurse who was on duty
19 for 12 of 18 Category A deaths, 9 of 10 Category B
20 deaths.

21 If we turn to Table 10, this is
22 similar to Table 9 but it looks instead at frequency
23 of nurses on duty within four hours prior to onset
24 of terminal events. There we observe similar trends.

25



Smith, Buehler
Wallace, Kusiac
dr.ex. (Lamek)

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FF8 2 (ANSWERS BY DR. BUEHLER)

3

There was one nurse who was on duty, Nurse 401, for
4 18 of 18 Category A deaths, 10 of 10 Category B
5 deaths, 4 of 8 Category C deaths, and so on.

6

If we turn to Table 11, we are now
7 looking at the rate of deaths during the time that
8 a nurse was on duty compared to the rate of deaths
during the time that the nurse was not on duty.

9

Q. Yes.

10

A. And we broke that down by
11 shifts. The relative risk is simply the rate that
12 occurred while the nurse was on duty divided by the
13 rate of deaths while the nurse was not on duty.

14

For Nurse 401, the relative risk
15 estimates - and this table is on the Category A
16 deaths alone - was infinity. That simply reflects
the fact that there were no deaths.

17

Q. No Category A deaths.

18

A. No Category A deaths that
19 did not occur within four hours of her being on duty,
and so on.

20

Do you want to go down the table
21 in more detail than this or is it adequate just to
22 explain what the table means?

23

Q. Perhaps you can just take the

24

25



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FF9 2

(ANSWERS BY DR. BUEHLER)

3 next nurse, 402, because there we do have some
4 numbers and we do have something to divide into.

5 A. Okay.

6 Q. Can you explain that line for
7 us?

8 A. Nurse 402 was on duty 657
9 hours during the day shift during that nine-month
10 period, and off-duty 2,643 hours. There were zero
11 Category A deaths that occurred within four hours
12 of her being on duty during the daytime and 2 that
13 occurred while she was off-duty. Therefore, the
14 rate while she was on duty was zero divided by
15 657, that value divided by 2, divided by 2,643
16 which is obviously zero.

17 On the night shift during that
18 nine-month period she was on duty 635.5 hours and
19 there were 12 deaths which occurred within four hours
20 of her being on duty during the night shift. There
21 were 4 deaths which occurred at times when she was
22 not at the Hospital within four hours of the child's
23 terminal onset, onset of terminal events. Therefore,
24 the rate while she was on duty was 12 divided by
25 635.5, that value divided by 4 over 2,664.5 or 12.6.

Q. Can I just understand one



FF10

1
2 (ANSWERS BY DR. BUEHLER)

3 thing, Dr. Buehler, please.

4 A. Yes.

5 Q. You are talking about the
6 onset of terminal events occurring within four hours
7 of a nurse's shift.

8 A. That is correct.

9 Q. Does that mean during a
10 nurse's shift or within four hours after its end?

11 A. That is correct. It could
12 have occurred either during -- yes.

13 Q. Okay.

14 A. But that is correct.

15 It is interesting to note however
16 that you might ask the question, what if the death
17 occurred five minutes after she got there?

18 Q. Yes.

19 A. And if you look at the
20 pattern of these deaths that is not an issue. The
21 nurses came on duty at 1930.

22 A. (Dr. Smith) That is right,
23 1930.

24 A. And in most cases these
25 deaths are occurring, are having onset of terminal
events after midnight, which is at least four hours



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FF11 2 (ANSWERS BY DR. BUEHLER)

3 after 1930. So that might be a concern that someone
4 would point out to us that was not in issue. So
5 we have relative risk of these events occurring
6 broken down by day shift, night shift and total.

7 THE COMMISSIONER: As I understand
8 the equation is 12 over 635.5?

9 DR. BUEHLER: Yes.

10 THE COMMISSIONER: Over, that is
11 the whole equation, over 2664.5; is that the way
12 it works out?

13 DR. BUEHLER: Correct.

14 THE COMMISSIONER: That will be
15 1 over 50, is that right, over 1 over 400. I am
16 trying to check this in the mathematics. It is
17 1 over 50 or 1 over 400 which makes it roughly
18 1 over 12; is that right, 1 over 8, that would make
19 it, is that right? I am just wondering how we
20 get to 12.6? What does it mean, the relative risk?

21 DR. BUEHLER: The relative risk is
22 an estimate of the strength of the association
23 between the presence of an individual and death
24 and you could say that for Nurse 401 the relative
25 risk was infinity; in other words, they all occurred
well within four hours of her being on duty. That is



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FF12 2 (ANSWERS BY DR. BUEHLER)

3 a very strong association, obviously. You don't
4 need statistics to tell you that.

5 THE COMMISSIONER: No, no, but
6 what is the 12.6? What does that mean? The relative
7 risk is 12.6 of what?

8 DR. BUEHLER: Okay. Actually, if
9 you are interested I can go through the arithmetic
step by step.

10 THE COMMISSIONER: Well I can do
11 the arithmetic but I don't know what to do with
12 the results.

13 DR. BUEHLER: Okay. That means that
14 the rate of death while she was on duty was 12.6
15 times greater than the rate of deaths that occurred
16 while she was not on duty.

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Smith, Buehler,
Wallace, Kusiak
dr. ex. (Lamek)

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M/PS

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THE COMMISSIONER: Yes, deaths on
duty. It was 12.6 times...

4

5

DR. BUEHLER: Greater than the rate of
deaths while she was not on duty.

6

MS. SYMES: Excuse me, would you just
do 402 nights, which numbers you plugged in to get to
12.6 again, please, I apologize.

7

DR. BUEHLER: I would be happy to. Is
there a blackboard available?

10

11

MR. LAMEK: There was but you are sitting
in its place now.

12

MS. SYMES: There is one here.

13

DR. BUEHLER: You were interested in
doing it for nurse 402 for the nighttime, is that
correct?

15

MS. SYMES: Yes, please.

16

DR. BUEHLER: There were 12 deaths that
occurred within 4 hours of her being on duty and she
was on duty for 635.5 hours. There were four deaths
which occurred while she was not on duty or not within
four hours, which is 2664.5. You have a calculator
handy?

21

MR. KUSIAK: I will do it. That 4 divided
by 2664.5, that is .001501 and the ratio is 0015 -- well,
I get 2 something. I must have made a mistake.

24

25



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2 THE COMMISSIONER: No, I can get it
3 without any trouble at all without using any calculator
4 at all. It is one over 50 over one over 600 which works
5 out as one over 50 times 600 over one and you get 12.
6 I have no trouble with it. That is because I never
7 learned a calculator.

8 DR. BUEHLER: That's the reason you
9 don't do arithmetic in front of an audience. Does that
10 answer the question that you asked?

11 MS. SYMES: Yes, thank you.

12 MR. YOUNG: Just for your reference,
13 Mr. Commissioner, I think the error made was Dr. Buehler
14 divided two into 635.5 instead of 12 and that's the
15 reason why it doesn't work.

16 DR. BUEHLER: Okay, shall we proceed?

17 MR. LAMEK: Q. I take it looking at
18 the T line under nurse 402 we now know to have been
19 Nurse Nelles. But looking at the total of the hours
20 she spent on duty, the hours that she spent off duty
21 in the epidemic period, the total number of deaths that
22 occurred while she was on duty are within four hours
23 of her being on duty, the total number of deaths that
24 occurred more than four hours after she went off duty,
25 your relative risk was 8.2, which as I understand you,
means that the death rate while she was on duty was



1

2 (ANSWERS BY DR. BUEHLER:)

3 8.2 times greater than it was when she was not on
4 duty in the totality for that nine month period. Do
5 I understand that correctly?

6 A. That is correct.

7 Q. Okay. And so on down through the
list of nurses.

8 A. In table 11 we have done similar
9 calculations for category B deaths, but by definition
10 the category B deaths all occurred on the night shift.
11 So, we have a rate only for night shift hours. And
12 then on the next page, table 11 continued. We have the
13 relative risk estimates for all deaths. If we look at
14 the individual nurses going down the list we see that,
15 for example, for nurse 401 during the day shift that
16 the death rate was 6.5 times greater during the days
17 that she was on compared to the days that she was not
on.

18 On the night shift the relative risk
19 was one to 1.5 times greater of a death occurring dur-
20 ing the night that she was no compared to the nights
21 that she was not on.

22 If you look at the relative risk regard-
23 less of day or night shift overall the rate of deaths
24 that occurred of all ward associated deaths during that

25



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2 (ANSWERS BY DR. BUEHLER:)

3 period was 33.3 times greater during the hours that
4 she was on duty compared to the hours that she was
not on duty. And you can go down the list.

5 On the next page we looked at informa-
6 tion that Dr. Kauffman provided us. There were
7 four deaths where he was able to provide an approximate
8 time of -- when digoxin may have been administered.
9 For the first one, case 02040, there were several
10 nurses who were on duty within that time period of
11 30 to 90 minutes before that child deteriorated. If
12 you look at those four deaths there was only one nurse
13 who was on duty at a time that all four of those
children died.

14 Q. I'm sorry, is that died or once
15 again the reference time?

16 A. No, I'm sorry. There was only
17 one nurse who was on duty at that time that Dr. Kauffman
18 estimated the digoxin overdose may have been
19 administered.

20 Q. Thank you.

21 A. Okay. Of these four patients
22 here, two of them are patients who were prescribed
23 digoxin -- I'm sorry, who were never prescribed
24 digoxin during their hospitalization, yet in whom

25



Smith, Buehler,
Wallace, Kusiak
dr. ex. (Lamek)

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2 (ANSWERS BY DR. BUEHLER:)

3 digoxin was found in post mortem tissues. That is
4 case 02040 and case 02064.

5 THE COMMISSIONER: Lombardo and Cook .

6 DR. BUEHLER: Yes, Lombardo and Cook .

7 There were two other patients who similarly had
8 digoxin detected in post mortem tissues in whom
9 digoxin had not been prescribed: Belanger, 02041 and
Hines 02057.

10 Again, if you look at those four
11 deaths separately, and this information is not presented
12 in total in this table, if you look at the four deaths
13 where digoxin was apparently inappropriately present
14 in post mortem tissues, again, there was only one
15 nurse who was on duty within four or within eight
16 hours for that matter of the time that those four
17 children died; that was nurse 401. I think it is
18 important to also look at the actual times that we
19 are dealing with here because it brings up the issue
20 that you raised earlier about other personnel. That
21 first case, Case 02040 is a child who suffered terminal
22 deterioration at 3:30 in the morning, 90 minutes before
23 that it is 2 in the morning.

24 The next case, 02061, is a child who
25 suffered terminal deterioration at 2:30 in the morning



Smith, Buehler,
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1

2 (ANSWERS BY DR. BUEHLER:)

3 and therefore 120 minutes before that would be
4 half past midnight.

5 The next case, Case 02065, is a
6 child who suffered terminal deterioration at
7 approximately 2:40 in the morning and 60 minutes
before that is 1:40.

8 The next child, 02064, is a child
9 who suffered terminal deterioration at approximately
10 4:18 and 60 minutes before that is 3:18.

11 Of the others that had inappropriate
12 digoxin, the other two, 02041, this is a child who
13 suffered terminal deterioration at 1930 in the evening
14 and if we were to, say, use an estimate of .4 hours,
15 or 8 hours for that matter, it would not get close to
midnight certainly.

16 Then, the last case that had inappropriate
17 digoxin present in tissues was 02057, the child who
18 had onset of terminal events at approximately 4:25;
19 4 hours before that would be approximately 30 minutes
after midnight.

20 Q. I'm sorry, you are going to have
21 to take me by the hand through that connective link.
22 You have pointed out all those times and referred to
23 something we said earlier.

24

25



1

2 (ANSWERS BY DR. BUEHLER:)

3 A. I think in particular the concern
4 is raised about looking at, for example, the people
5 who picked up garbage at midnight or the person who
6 picked up the NARvel scores at approximately midnight.
7 It is difficult to see, given what Dr. Kauffman has
8 told us about possible times of digoxin overdose,
9 that that person could be associated with a death that
occurred at 1930 in the afternoon-- in the evening, yes.

10 Q. Yes.

11 A. The other point is that our
12 understanding is that most other ancillary personnel
13 go off duty at approximately 10 or 11:00 at night.

14 Q. Yes.

15 A. And therefore at the outside
16 11:00 at night is several hours after these times.
17 I think it is also important to mention that these
18 times are clearly approximate estimates that Dr.
Kauffman made.

19 Q. Yes. Doctor, in each of the
20 tables that you discussed, 9, 10, 11, certainly those
21 three, and to an extent table 4, do they not reflect
22 as one would expect that the members of the same nursing
23 team, whether it be the Trayner nursing team or any
other, tend to be grouped together in your table of

24

25



1

2 (ANSWERS BY DR. BUEHLER:)

3 frequency of presence?

4 A. That is correct.

5 Q. For example, once I have gone
6 past 401, 402, 403, 404, whom we know to be respectively
7 Trayner, Nelles, Scott and Christie, I then get into
8 the members of the 4-B team who were usually on duty at
the same time as that team.

9 A. That is correct.

10 Q. Okay.

11 A. And your comment brings to mind
12 another important factor and, that is, in doing these
13 assessments we considered any nurse on 4A or 4B to
have potential access to a patient on either 4A or
14 4B.

15 Q. Okay. Well, do I understand,
16 Doctor, this perhaps comes to two propositions, that
17 in the first place there is one person and, that is
to say, Nurse Trayner who, on the data available to you,
18 appears to have been present for all category A and
category B deaths.

19 A. That is correct.

20 Q. But your finding goes no further
21 than that, does it, and there is no suggestion that
22 constant presence of that one nurse therefore indicates

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Smith, Buehler,
Wallace, Kusiak
dr. ex. (Lamek)

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2 access by that one nurse to those children?

3 A. That is a very important point
4 and that is correct.

5 Q. Okay.

6 A. I would add to that that these
7 are associations.

8 Q. Yes, they are merely indications
9 of who was present.

10 A. That is correct.

11 MR. LAMEK: Mr. Commissioner, I am about
12 to go to the wrap up matters, the mortality considera-
13 tions in the summer of '82 and the conclusions and
14 summary, can I complete it in the morning, please?

15 THE COMMISSIONER: All right, 10:00
16 tomorrow morning, then.

17 MR. LAMEK: Thank you.

18 THE COMMISSIONER: I should say that
19 I don't know what the proceedings are going to be, but
20 I understand that Mr. Roland and Mr. Scott will not
21 be available tomorrow.

22 MR. ROLAND: That is correct, Mr.
23 Commissioner, if we could be put over to Wednesday I
24 would appreciate it.

25 THE COMMISSIONER: Yes. Well, I don't
think there will be that much trouble as long as there



Smith, Buehler,
Wallace, Kusiak
dr. ex. (Lamek)

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2 are counsel prepared to go on. Ms. Symes, are you
3 prepared to go on tomorrow?

4 MS. SYMES: I will make myself prepared.

5 THE COMMISSIONER: Yes. Mr. Young,
6 are you ready to go on tomorrow if need be?

7 MR. YOUNG: I expect that I can be,
Mr. Commissioner.

8 THE COMMISSIONER: Yes, all right. Well,
9 I think that will solve our problem.

10 MS. SYMES: Excuse me, could you give
11 an indication as to the order, Mr. Commissioner, will
12 it be the normal order?

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3 THE COMMISSIONER: The order will
4 be, as I understand it, Mr. Brown will be first. Is
5 that correct?

6 MR. BROWN: If we cross-examine,
7 Mr. Sopinka would like to do it. He is unavailable
8 tomorrow and would ask to be stood down till
9 Wednesday.

10 THE COMMISSIONER: All right.
11 Well now, Mr. Hunt, can you start off?

12 MR. HUNT: Yes, sir.

13 THE COMMISSIONER: All right. And
14 after that then it will be Miss Symes I think?

15 MS. SYMES: Normally you go this
16 way but...

17 THE COMMISSIONER: I don't always.
18 You can't trust me but if you want I will ask
19 Mr. Young if he will go next. Or, no, I guess
20 Mr. Ortved, you are next in line, are you?

21 MR. ORTVED: Yes.

22 THE COMMISSIONER: Are you happy
23 to go?

24 MR. ORTVED: Absolutely.

25 THE COMMISSIONER: And Mr. Young?

MR. YOUNG: Yes.

THE COMMISSIONER: Miss Symes, will



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you fit in there?

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MS. SYMES: Yes.

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THE COMMISSIONER: All right. Then,
Mr. Knazan, if you come on tomorrow are you ready
to go?

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MR. KNAZAN: Yes, I will be
prepared, sir.

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THE COMMISSIONER: All right. And,
Mr. Olah, are you ready?

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MR. OLAH: I guess I will have to
be, sir.

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THE COMMISSIONER: Well, I think
I would like you to be ready, and that means I
think that will keep us occupied, but I will proceed
with... Then by that time Mr. Sopinka will be here
for whatever the day is, Wednesday; is that right?

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MR. BROWN: That is right.

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THE COMMISSIONER: And thereafter
as required as the subpoenas say?

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MR. BROWN: Hopefully.

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